NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

March 6 - 7, 2024

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

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

Nevada State Board of Pharmacy

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

Date Posted: February 21, 2024

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, March 6, 2024, at 9:00 am. The meeting will continue Thursday, March 7, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

3. Approval of the January 17-18, 2024, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

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

   A. Pacific Medical, Inc (Northern NV Sierra) – Reno, NV
   B. Pacific Medical, Inc (Renown S Meadows) – Reno, NV
   C. Vantive US Healthcare, LLC – Largo, FL

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

   Background Check Not Required by Law.

   4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

   4.2.2 Manufacturer (NAC 639.593(7)(d))

   D. ALOM Technologies Corporation – Indianapolis, IN
   E. Aphena Pharma Solutions – Cookeville, TN
   F. BE Pharmaceuticals, Inc – Cary, NC
   G. DMG America, LLC – Englewood, NJ
   H. Embody, Inc – Norfolk, VA
   I. Emmaus Medical, Inc – Torrance, CA
   J. Impladent Ltd – Jamaica, NY
   K. Maclean Health – Sacramento, CA
   L. Progressive Medical, Inc – Fenton, MO
   M. RVL Pharmaceuticals, Inc – Bridgewater, NJ
   N. Seagen Inc – Bothel, WA
   O. Seagen Inc – Bothel,WA
   P. Time-Cap Laboratories, Inc – Melville, NY
   Q. Vantive US Healthcare, LLC – Largo, FL
   R. X4 Pharmaceuticals, Inc – Boston, MA

   4.2.3 Publicly Traded (NAC 639.593(7)(a))

S. Animal Health International, Inc – Ontario, CA
T. Animal Health International, Inc – Twin Falls, IN
U. Cintas Corporation No. 2 – Sparks, NV
V. Zoetis US LLC – Lee's Summit, MO

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

W. Morris & Dickson Co., LLC – Shreveport, LA
X. M&D Specialty Distribution, LLC – Shreveport, LA

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

Y. Delcath System, Inc – Queensbury, NY
Z. The J. Molner Company, LLC – Jersey City, NJ
AA. Verastem Oncology – Needham, MA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

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

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

BB. AnovoRx Distribution, LLC – Chandler, AZ

4.3.1 Manufacturer (NAC 639.593(7)(d))

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

CC. City Pharmacy II – Las Vegas, NV
DD. ER at Cadence - Henderson, NV
EE. ER at Desert's Edge – Las Vegas, NV
FF. Ok'Care Pharmacy – Las Vegas, NV

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

GG. Apothecary Options – Chico, CA
HH. King's Pharmacy & Compounding Center – Irvine, CA
II. RPC2B, LLC – Millburn, NJ
JJ. Undefined Pharmacy, LLC – Warren, NJ

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

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

KK. 14H Pharmacy, LLC – Riverside, CA
LL. Access Therapy Center – Pittsburgh, CA
MM. BioPlus Specialty Pharmacy Services, LLC – Indianapolis, IN
NN. BioPlus Specialty Pharmacy Services, LLC – St. Louis, MO
OO. Cardinal Health Pharmacy Services, LLC – Dublin, OH
PP. CarelonRx Pharmacy, Inc – Grand Prairie, TX
QQ. Nomi Health Pharmacy – Salt Lake City, UT
RR. Norco Inc – Boise, ID
SS. PersonalRx – East Rutherford, NJ
TT. Quality Drug Corporation – Irvine, CA

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

UU. Pacific Medical, Inc – Carson City, NV

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

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

VV. Las Vegas Institute for Advanced Surgery – Las Vegas, NV
WW. Nevada Surgical Suites – Las Vegas, NV
XX. Nevada Surgical Suites – Las Vegas, NV
YY. Nevada Surgical Suites – Las Vegas, NV

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

ZZ. Gabriela Castillo R – Pharmaceutical Technician
AAA. Sammie Sok – Pharmaceutical Technician
BBB. Tiffany Michelle James – Pharmaceutical Technician
CCC. Terry Muratore – Controlled Substance
DDD. Terry Muratore – Veterinarian Dispense

◈ REGULAR AGENDA ◈

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

A. CVS Pharmacy #9967	(19-049-PH-S)
B. Mihreteab Tesema	(19-049-RPH-S)
C. ASP Cares Pharmacy	(19-011-PH-S)
D. Venus Vedadi	(19-011-RPH-S)
E. Jay Selznick	(19-043-CS-N)
F. Kochy Tang	(19-126-CS-S)
G. Ryan Ross	(20-027-PT-S)
H. Ajumobi Agu	(22-535-CS-S)
I. Monivirin Son	(23-046-CS-S)
J. Matthew Okeke	(19-013-CS-S)
K. DVH Hospital Alliance	(22-053-PH-S)
L. Marissa Crain	(22-053-PT-S)
M. Elliott Asarch	(22-053-RPH-A-S)
N. Matthew Huntington	(22-053-RPH-B-S)
O. Cheryl Saunders	(23-167-CS-N)
P. Matthew Kikuchi	(21-087-CS-N)
Q. Plus One Pharmacy	(21-189-PH-S)
R. Maurice Vargas	(21-086-CS-N)
S. Candice Denham	(23-257-CS-S)
T. Walgreens Pharmacy #05479	(21-169-PH-S)
U. Walgreens Pharmacy #02445	(21-169-PH-O)
V. Grace Opulencia	(21-169-RPH-S)
W. John Tolentino	(22-021-CS-S)
X. Wal-Mart Pharmacy #10-4239	(22-089-PH-N)
Y. CVS Pharmacy #8821	(23-126-PH-S)
Z. Eugene Bondoc Naval	(23-126-RPH-S)

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

    A. Sunrise Respiratory Care, Inc – Las Vegas, NV

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

    A. Las Vegas Community Pharmacy – Las Vegas, NV
    B. Nevada Specialty Pharmacy – Las Vegas, NV
    C. Trinity Pharmacy – Las Vegas, NV
    D. Trusted Care Pharmacy – Henderson, NV

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

    A. Vital Care of Henderson – Henderson, NV

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

A. Med-Plus Pharmacy – Livermore, CA
B. Polaris Pharmacy Services – Covina, CA
C. Seven Hills Pharmacy – Sharronvile, OH
D. Woman's International Pharmacy, Inc – Youngstown, AZ

10. Request for Pharmacist Application to Retake the Nevada MPJE Exam (NRS 639.120(1)) – Appearance (**FOR POSSIBLE ACTION)**

    A. Rakan Sayegh

11. Application for Pharmacist Registration Renewal (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    A. HaiDuong Ngo
    B. Roland Israel
    C. Tony Hieu La

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

    A. Morgan Alexis Miller

13. Application for Dispensing Practitioner Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

    A. David Lanzkowsky

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

    A. Chasity Beene

◈ WORKSHOP ◈

Thursday, March 7, 2024 – 9:00 am

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

    A. **Amendment to Nevada Administrative Code (NAC) 639**. The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.

    B. **Amendment to Nevada Administrative Code (NAC).** The proposed amendments establishes the registration requirements for certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to

chapter 630 or 633 or NRS, to order, prescribe, possess, and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.

C. **Amendment to Nevada Administrative Code (NAC) 453.** The proposed amendments relate to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I.

D. **A REGULATION relating to pressurized stocking.** Allowing pressurized stocking to be provided without a prescription in certain circumstances.

◈ PUBLIC HEARING ◈

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

    A. **Amendment of Nevada Administrative Code (NAC) 453.540: Schedule IV**. The proposed amendment to NAC 453.540 will add zuranolone to the list of controlled substances listed in Schedule IV.
    (LCB File No. R144-23)

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

18. Executive Secretary Report:

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

19. Date and Location of Next Scheduled Board Meeting:

    April 17-18, 2024 – Reno, NV

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

21. Adjournment

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

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

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

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

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NEVADA STATE BOARD OF PHARMACY

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

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

• Web Page: bop.nv.gov

MINUTES

January 17-18, 2024

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, January 17, 2024, at 9:00 am. The meeting will continue Thursday, January 18, 2024, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Board Members Present:

Helen Park	Krystal Freitas	Jade Jacobo	Wayne Mitchell
Richard Tomasso	Gener Tejero		

Board Members Not Present:

Rolf Zakariassen

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Gus Vanderdonck
Brett Kandt	Gregory Zunino	Darlene Nases	Joe Dodge
Darla Zarley	Leo Basch	Kenneth Scheuber	Dena McClish
Rosalie Bordelove			

DRAFT

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Open Meeting Laws for Nevada.

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

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

2. Public Comment January 17, 2024, 9:00 AM

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, read a written public comment into record.

James Boyle requests that the Board of Pharmacy amend NAC 639.69545 (Pressurized Stockings) such that consumers are permitted to purchase stockings with a pressure rating of 30mmHG, or less, without an order from a practitioner.

◈ CONSENT AGENDA ◈

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

3. Approval of the December 6-7, 2023, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to approve December 6-7, 2023, Board Meeting minutes.

Second: Krystal Freitas

Action: Passed unanimously.

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

A. Darah Medical Equipment and Supplies, LLC – Maumee, OH
B. Providence Home Medical LP – McMurray, PA

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

Background Check Not Required by Law.

4.2.1 Distributor for Single Manufacturer (NAC 639.593(7)(e))

4.2.2 Manufacturer (NAC 639.593(7)(d))

C. Almac Pharma Services, LLC – Audubon, PA
D. Civica, Inc – Petersburg, VA
E. Exelead Inc – Indianapolis, IN
F. Medtronic USA, Inc – Memphis, TN
G. Meitheal Pharmaceuticals, Inc – Chicago, IL
H. MicroSurgical Technology, Inc – Redmond, WA
I. Radius Health, Inc – Boston, MA
J. Slayback Pharma, LLC – Princeton, NJ
K. Sumitomo Pharma America, Inc – Marlborough, MA
L. Valinor Pharma, LLC – Bedminster, NJ

4.2.3 Publicly Traded (NAC 639.593(7)(a))

M. Pfizer Inc – Pleasant Prairie, WI

4.2.4 VAWD-Accredited (NAC 639.593(7)(c))

N. Pharma Logistics, LLC – Libertyville, IL

4.2.5 Manufacturer and VAWD-Accredited (NAC 639.593(7)(c) and (d))

4.2.6 Publicly Traded and Manufacturer (NAC 639.593(7)(a) and (d))

O. Eyenovia – Redwood City, CA
P. Karuna Therapeutics, Inc – Boston, MA
Q. Spectrum Pharmaceuticals, Inc – Irving, CA

4.2.7 Publicly Traded and VAWD-Accredited (NAC 639.593(7)(a) and (c))

4.2.6 Background checks completed in compliance with NRS 639.500.

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

R. Axelara, Inc – San Antonio, TX
S. Crane Worldwide Logistics, LLC – Houston, TX
T. Veterinary Service, Inc – Visalla, CA

4.3.1 Manufacturer (NAC 639.593(7)(d))

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

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

U. Apostrophe Pharmacy LLC – Gilbert, AZ
V. Musely Compounding Pharmacy East LLC – Suwanee, GA
W. The Transplant Pharmacy – Flowood, MS
X. Vital Choice Specialty Pharmacy – Mesa, AZ

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

Y. BioPlus Specialty Pharmacy Services, LLC – Denver, CO
Z. Healthcare Evolution, LLC – Royersford, PA
AA. Heartland Veterinary Pharmacy – Hastings, NE
BB. HomeFree Pharmacy Services – Indianapolis, IN
CC. Kroger Health Connect – Blue Ash, OH
DD. Omro Meds – Omro, WI

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

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

EE. Maribeth Moran

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

FF. Cynthia Hewlett
GG. Jesse James Bradberry
HH. Gabrielle Townsley

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda.

Second: Wayne Mitchell

Action: Passed unanimously.

◈ REGULAR AGENDA ◈

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

J. Sheryl Cipollini (22-437-CS-S)

Sheryl Cipollini appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Ms. Cipollini related to dispensing prescription drugs without a dispensing registration.

Mr. Zunino presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Ms. Cipollini Certificate of Registration No. CS30592 and CS24985 are the following: 1) pay a fine of $5,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

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

Second: Wayne Mitchell

Action: Passed unanimously.

L. Care Direct Rx, LLC (22-165-PH-O)

Laura Lucero appeared as counsel on behalf of Care Direct Rx, LLC.

Gus Vanderdonck, Assistant General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Care Direct Rx, LLC due to their failure to disclose pending discipline on their 2020 business renewal application.

Mr. Vanderdonck presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Care Direct Rx, LLC, License No. PH03043, are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially reimburse the

Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Ms. Lucero clarified that their license hadn't lapsed but was on an "inactive" status. Once they reapplied, the license was reactivated. Ms. Lucero believes that the error was an oversight.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Care Direct Rx, LLC, as presented by Mr. Vanderdonck.

Second: Wayne Mitchell

Action: Passed unanimously.

P. Poncia Reed, APRN (20-157-CS-S)

Poncia Reed appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, presented the case against Ms. Reed on behalf of his co-counsel, Peter Keegan.

Mr. Kandt prosecuted the case alleging the respondent allowed her medical assistant to prescribe controlled substances with a signature stamp.

Mr. Kandt presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Ms. Reed, Certificate of Registration No. CS23722, are the following: 1) pay a fine of $1,500 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Ms. Reed provided a statement to the Board.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order's for Poncia Reed as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

A. CVS Pharmacy #8794 (19-134-PH-S)

Jade Jacobo recused herself due to her employment with CVS Health.

Brian Convery, CVS Representative, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #8794 alleging a misfill of Estradiol 0.5mg and failure to counsel patient, which resulted in patient harm.

Mr. Kandt presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for CVS Pharmacy #8794 License No. PH01405 are the following: 1) pay a fine of $3,000 for the violations; and 2) pay $2,000 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order's for CVS Pharmacy #8794 as presented by Mr. Kandt.

Second: Wayne Mitchell

Action: Passed unanimously (Jacobo recused).

B. CVS Pharmacy #8798 (19-267-PH-S)
C. Joyce Suarez Cabrera, RPH (19-267-RPH-S)

Jade Jacobo recused herself due to her employment with CVS Health.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #8798 alleging that CVS Pharmacy #8798 employees failed to dispense Doxycycline 50mg with another prescription Metronidazole 250 mg which were supposed to be taken simultaneously as the prescribed course of treatment.

Mr. Kandt presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Ms. Suarez Cabrera Certificate of Registration No. 17102 are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially

reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

The proposed stipulated penalties for CVS Pharmacy #8798 License No. PH01094 are the following: 1) pay a fine of $2,000 for the violations; and 2) pay $1,000 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Joyce Suarez Cabrera appeared and was sworn in by President Park prior to answering questions and offering testimony.

Brian Convery, CVS Representative, appeared and President Park commented that Mr. Convery is still sworn in from a previous matter.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Stipulation and Order's for CVS Pharmacy #8798 and for Joyce Suarez Cabrera as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo recused).

E.	CVS Pharmacy #8819	(19-060-PH-S)
F.	Thuytrang Huynh, RPH	(19-060-RPH-A-S)
G.	Michael Willson, RPH	(19-060-RPH-B-S)

Jade Jacobo recused herself due to her employment with CVS Health.

Thuytrang Huynh and Michael Willson both appeared and were sworn in by President Park.

Brian Convery, CVS Representative, appeared and President Park commented that Mr. Convery is still sworn in from a previous matter.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that a prescription for magic mouth was given to the incorrect patient.

Mr. Zunino presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for CVS Pharmacy #8819, License No. PH02047, are the following: 1) pay a fine of $2,000 for the violations; and 2) pay $350 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

The proposed stipulated penalties for Thuytrang Huynh, Certificate of Registration No. 14865, are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $350 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

The proposed stipulated penalties for Michael Willson, Certificate of Registration No. 08572, are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $350 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order's for CVS Pharmacy #8819, Thuytrang Huynh, and Michael Willson as presented by Mr. Zunino.

Second: Wayne Mitchell

Action: Passed unanimously (Jacobo recused).

Q.	CVS Pharmacy #8821	(23-126-PH-S)
R.	Eugene Bondoc Naval	(23-126-RPH-S)

Jade Jacobo recused herself due to her employment with CVS Health.

Eugene Bondoc Naval appeared and was sworn in by President Park.

Brian Convery, CVS Representative, appeared and President Park commented that Mr. Convery is still sworn in from a previous matter.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Mr. Naval on behalf of his co-counsel, Peter Keegan.

Mr. Kandt prosecuted the case alleging that during a board inspection, the pharmacist to pharmacy tech ratio was exceeded per Nevada law.

Mr. Kandt presented a Stipulation and Order for the Board's consideration.

The proposed stipulated penalties for Eugene Bondoc Naval, Certificate of Registration No. 19578, are the following: 1) pay a fine of $1,500 for the violations; and 2) pay $250 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

The proposed stipulated penalties for CVS Pharmacy #8821, License No. PH01095, are the following: 1) pay a fine of $6,000 for the violations; and 2) pay $750 to partially reimburse the

Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to reject the Stipulation and Order's for CVS Pharmacy #8821 and Eugene Bondoc Naval as presented by Mr. Kandt.

Second: Gener Tejero

Board discussion ensued.

Aye: Tejero, Freitas, and Mitchell
Nay: Park and Tomasso

Action: Motion carries (Jacobo recused).

This matter will go into a hearing and is continued to a future board meeting.

H. CVS Pharmacy #2989 (20-011-PH-S)

Jade Jacobo recused herself due to her employment with CVS Health.

Brian Convery, CVS Representative, appeared and President Park commented that Mr. Convery is still sworn in from a previous matter.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against CVS Pharmacy #2989 alleging a misfill of Clonazepam 0.5mg instead of Ibuprofen and Amoxicillin.

Mr. Zunino presented a Stipulation and Order for the Board's consideration.

With Mr. Convery's consent, Mr. Zunino proposed amendments to paragraph 7 and 8 of the stipulation, including an amendment to reflect that discipline will be imposed only for Count One of the Accusation. As amended, the proposed stipulated penalties for CVS Pharmacy #2989 are the following: 1) pay a fine of $1,000 for the violations; and 2) pay $500 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board discussion ensued.

Board Action:

Motion: Gener Tejero moved to approve the amended Stipulation and Order for CVS Pharmacy #2989 as presented by Mr. Zunino.

Second: Krystal Freitas

Action: Passed unanimously (Jacobo recused).

M. Efrain Armenta, RPH (23-187-RPH-S)

No representative was present on behalf of Efrain Armenta.

Gus Vanderdonck, Assistant General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding CE audit. Mr. Armenta failed to comply with biennial pharmacist registration for CE requirements.

Mr. Vanderdonck requested a default against Mr. Armenta due to his failure to appear and several attempts at service.

Mr. Vanderdonck requested that Exhibit 1-4 be entered into the record.

President Park admitted as Exhibits 1-4.

Mr. Vanderdonck requested the Board revoke Certificate of Registration No. 19224, effective immediately, and that the respondent cannot reapply for reinstatement for a period of one year.

Board discussion ensued.

Board Action:

Motion: Wayne Mitchell moved to find that respondent was properly served and noticed of the hearing.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: Wayne Mitchell moved to accept the allegations in the Order as true.

Second: Jade Jacobo

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to revoke Efrain Armenta's Certificate of Registration No. 19224 and cannot reapply for reinstatement for a period of one year.

Second: Wayne Mitchell

Action: Passed unanimously.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to award the attorney's fees and costs of $506.67 on the basis that they were reasonable, necessary, and actually incurred.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved that the Board Order is effective immediately.

Second: President Park

Action: Passed unanimously.

N. Juliana Izevbigie, RPH (23-193-RPH-S)

No representative was present on behalf of Juliana Izevbigie.

Gus Vanderdonck, Assistant General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding CE audit. Ms. Izevbigie failed to comply with biennial pharmacist registration for CE requirements.

Mr. Vanderdonck requested a default against Ms. Izevbigie due to her failure to appear after several attempts of service.

Mr. Vanderdonck requested that Exhibit 1-4 be entered into the record.

President Park admitted Exhibits 1-4.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that respondent was properly served and noticed of the hearing.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to accept the allegations in the Order as true.

Second: Wayne Mitchell

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to revoke Juliana Izevbigie's Certificate of Registration No. 09672, effective immediately, and that the respondent cannot reapply for reinstatement for a period of one year.

Second: Wayne Mitchell

Action: Passed unanimously.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to award the attorney's fees and costs of $506.67 on the basis that they were reasonable, necessary, and actually incurred.

Second: Wayne Mitchell

Action: Passed unanimously.

O. Odette Erian, RPH (23-196-RPH-S)

Jade Jacobo disclosed that Ms. Erian was a former colleague, but she can participate fairly and without bias.

Gus Vanderdonck, Assistant General Counsel for the Nevada Board of Pharmacy, prosecuted the case regarding CE audit. Ms. Erian failed to comply with biennial pharmacist registration for CE requirements.

Mr. Vanderdonck requested that Exhibit 1-4 be admitted.

President Park admitted as Exhibits 1-4.

Mr. Vanderdonck requested that the Board makes a motion that the respondent was properly served and notified of the hearing to the last address of record consistent with Nevada law.

Board Action:

Motion: Jade Jacobo moved that the respondent was properly served and notified of the hearing to the last address of record consistent with Nevada law.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Vanderdonck requested the Board make the Findings of Fact of the Order accepted as true.

Board Action:

Motion: Jade Jacobo moved that the Findings of Fact of the order accepted as true.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Vanderdonck requested the Board revoke Certificate of Registration No.16558, effective immediately, and that the respondent cannot reapply for reinstatement for a period of one year.

Board Action:

Motion: Jade Jacobo moved to revoke Certificate of Registration No.16558, effective immediately, and that the respondent cannot reapply for reinstatement for a period of one year.

Second: Krystal Freitas

Action: Passed unanimously.

Mr. Vanderdonck requests that the Board find the attorney's fees and costs of $506.67 on the basis that they were reasonable, necessary, and actually incurred.

Board Action:

Motion: Jade Jacobo moved to award the fees and costs of $506.67 on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

D. Carrie Lambert, DVM (22-484-DV-N)

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, stated that Ms. Lambert has become compliant with the Stipulation and Order and requested that the hearing on the Order to Show Cause be vacated.

President Park vacated the Order.

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

No representative was present on behalf of Matthew Okeke.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case against Dr. Okeke, alleging prescribing of controlled substances while out of the country and Medicaid fraud.

Mr. Zunino called Shirley Hunting, Board Coordinator for the Nevada Board of Pharmacy, to be called as a witness.

Ms. Hunting appeared and was sworn in by President Park.

Mr. Zunino questioned Ms. Hunting on the service of the Notice of Intended Action and Accusation.

Mr. Zunino requested President Park to enter Exhibit 1, the documentation showing the serving of the Accusation into the record.

President Park admitted Exhibit 1.

Mr. Zunino requested President Park enter Exhibit 2, the email correspondence between Mr. Zunino and the respondent's attorney, Mr. Agwara, acknowledging that Dr. Okeke is his client.

Mr. Zunino requested Exhibit 2 to be entered into the record.

President Park admitted Exhibit 2.

Mr. Zunino requested that the Board find that respondent and his counsel were properly served with the accusation and notified of the hearing to the last address of record consistent with Nevada law.

Board Action:

Motion: Jade Jacobo moved to find that respondent was properly served and noticed of the hearing.

Second: President Park

Action: Passed unanimously.

Mr. Zunino requested that President Park enter Exhibit 3 and Exhibit 4 into the record.

President Park admitted Exhibit 3 and Exhibit 4.

Mr. Zunino requested that the Board adopt the allegations and Accusation as true and to impose the following discipline for Dr. Okeke: 1) revoke Certificate of Registration No. CS10935, effective immediately, with the ability to reapply after one year; and 2) pay $2,500 in fines; and 3) pay $1,754.68 to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

Board Action:

Motion: Jade Jacobo moved to make the Findings of Fact consistent with paragraphs 3-18 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make Conclusions of Law consistent with paragraphs 19-26 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Dr. Matthew Okeke guilty of Counts 1-9 of the Notice of Intended Action and Accusation.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to revoke Dr. Matthew Okeke's Certificate of Registration No. CS10935, effective immediately, and that the respondent cannot reapply for reinstatement for a period of ten years.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to impose a fine against Dr. Matthew Okeke of $2,500 for the violations.

Second: President Park

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to award the fees and costs of $1,754.68 on the basis that they were reasonable, necessary, and actually incurred.

Second: Krystal Freitas

Action: Passed unanimously.

K. Plus One Pharmacy (21-189-PH-S)

This matter was continued to the March Board Meeting.

I. Anqi Liu (20-011-RPH-S)

This matter has been dismissed.

20. Executive Secretary Report:

A. Financial Report

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented the Executive Secretary Financial Report to the Board's satisfaction.

Board discussion ensued.

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

B. Eclipse Durable Supplies, LLC – Las Vegas, NV

Isadoris Otano Gutierrez, Owner, and Adrianna Lopez, Owner and Administrator, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Gus Vanderdonck presented background on the application and questioned their business model and how they intend to get business.

Ms. Gutierrez and Ms. Lopez answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Medical, Devices, Equipment and Gases License for Eclipse Durable Supplies, LLC, pending a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

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

B. Lyfe Pharmacy – Las Vegas, NV

Nazokat Nigmatova, Owner and Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

President Park disclosed that she knows the Managing Pharmacist, Nazokat Nigmatova, but can participate fairly and without bias.

Yenh Long, Deputy Secretary for the Nevada Board of Pharmacy, presented background on the application and questioned Ms. Nigmatova on her experience and the business model.

Ms. Nigmatova answered questions to the Board's satisfaction.

Jade Jacobo questioned Ms. Nigmatova's work history as Managing Pharmacist at Evergreen Pharmacy.

Joe Dodge, Inspector for the Nevada Board of Pharmacy, commented that he completed an inspection at Evergreen and Ms. Nigmatova was not listed as Managing Pharmacist at that time.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Pharmacy License for Lyfe Pharmacy pending a favorable inspection, additional quarterly inspections at

the expense of the owner for the first year, and an updated application with the new pharmacy address and Ms. Nigmatova's updated work history.

Second: Richard Tomasso

Action: Passed unanimously.

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

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

Richard Tomasso was excused from the Board Meeting at 2:37PM.

Alia Najjar, counsel for Ajumobi Agu, appeared and made a request to the Board.

Alia Najjar believed that she had direct conflict to represent the respondent based on the requested documents she received. She contacted Mr. Agu yesterday to notify him of the need to retain new counsel.

Board discussion ensued.

Richard Tomasso returned to the Board Meeting at 2:41PM.

President Park granted a continuance on this matter to the March 6, 2024, Board meeting.

U. Monivirin Son, MD (23-046-CS-S)

This matter was continued to a future Board meeting.

17. Review and Approval of Continuity of Service Incentives to be added to the Policy Manual **(FOR POSSIBLE ACTION)**

Dave Wuest presented the agenda item to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: President Park moved to add the Continuity of Service Incentives to the policy manual.

Second: Wayne Mitchell

Action: Passed unanimously.

14. Approval of the Facility for Treatment with Narcotics Application **(FOR POSSIBLE ACTION)**

Yenh Long presented the amended Facility for Treatment with Narcotics Application to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the amended Facility for Treatment with Narcotics Application as presented by Ms. Long.

Second: Jade Jacobo

Action: Passed unanimously.

20. Executive Secretary Report:

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

Dave Wuest presented his Executive Secretary Report to the Board's satisfaction.

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

Gregory Zunino and Brett Kandt presented the General Counsel Report to the Board's satisfaction.

16. Approval of the CRNA Controlled Substance Application **(FOR POSSIBLE ACTION)**

Yenh Long presented the background of the proposed application for Board approval. Ms. Long references sections of the bill that was passed which will allow CRNA's to prescribe and order drugs under certain circumstances.

Board staff answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the CRNA Controlled Substance Application as presented by Ms. Long.

Second: Krystal Freitas

Action: Passed unanimously.

Public Comment January 17, 2024, 3:06 PM

There was no public comment.

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

Board Members Present:

Helen Park	Krystal Freitas	Jade Jacobo	Wayne Mitchell
Richard Tomasso	Gener Tejero		

Board Members Absent:

Rolf Zakariassen

Board Staff Present:

Dave Wuest	Yenh Long	Shirley Hunting	Gus Vanderdonck
Brett Kandt	Gregory Zunino	Darlene Nases	Joe Dodge
Darla Zarley	Leo Basch	Kenneth Scheuber	Dena McClish

President Park read the mission statement of the Nevada State Board of Pharmacy to reiterate the Board's duty to carry out and enforce the provisions of Nevada Law to protect the health, safety, and welfare of the public.

Dave Wuest stated that this Board Meeting is being held over Zoom and is in compliance with the Open Meeting Laws for Nevada.

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment January 18, 2024, 9:00 AM

There was no public comment.

◈ Workshop ◈

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

C. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.

Joe Dodge, Inspector for the Nevada Board of Pharmacy, provided a timeline of USP events and discussions that took place prior to the publication of the revised USP Chapters 797.

Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented background on proposed regulation workshop item.

President Park opened the floor to public comment.

Mr. Wuest presented three written public comments to the Board.

Chad Baker, Senior Vice President of Government Relations at Flavor Rx, commented that statistics show that a large amount of Nevada pharmacies, along with multiple pharmacies across the country, provided medication flavoring to at least 2 million children's medications with no incidents of harm being reported, and that flavoring improves the taste of the medicine.

Lori Walmsley, Director of Pharmacy at Walgreens, is in support of Mr. Baker's comments. Ms. Walmsley believes that it is worthwhile to think about whether there should be other exclusions from USP 795 standards. Ms. Walmsley is concerned that products will not be available as much as they should be for patients. Her alternative thought was to adopt USP standards but create different categories, and referenced Mississippi's carve out as an example. From an operating standpoint, if flavoring becomes compounding, then you must have a patient-specific order from a prescriber.

Ken Kunke from the Nevada Pharmacy Alliance asked the Board that these changes can affect businesses compounding in Nevada. He encouraged the Board to take the implementation of the USP standards slowly, as any adaptation could cause pharmacies to be afraid of doing simple compounding and patient access may be harmed in the long run.

Matt Sarso, Owner of Solutions Specialty Pharmacy, references guidelines added to USP that could affect how much patients are charged for their medications.

Mr. Sarso read a patient letter into the record.

Mark Johnson, Pharmacist with CVS Health, commented that if flavoring becomes compounding, then the prescriber will have to authorize each compounding.

Liz MacMenamin from the Retail Association of Nevada agreed with the comments of those who spoke before her. She appealed to the Board to listen to the concerns, take the time to understand the impact, and look at the problems that have happened in California. The implementation of these standards could limit patient access, and specifically will limit medications for children.

Mr. Wuest commented that the USP standards have already been adopted, but that the Board staff's intent is to provide clarity, not just to race into implementation of the standards.

Mr. Dodge read the adopted USP standards on flavoring for clarification and shared why the USP has made the determination that flavoring is compounding. He cautioned the Board that if they were to make any exemptions that were less stringent than what USP has published, then there must be strong scientific evidence to support it.

Sean Barclay, Pharmacist at Meta Pharmacy Services, commented that the FDA already put this in motion, and they would determine whether pharmacies are following regulations. All changes will be difficult to institute flavoring and would be a re-training of prescribers.

Mr. Dodge commented that two new USP chapters went into effect that haven't been discussed. USP 800 was specific to hazardous compounding, and USP 825 was specific to radio pharmaceuticals.

Richard Tomasso was excused from the meeting at 9:59AM.

Gener Tejero, Pharmacist, entered two written letters into the record that he received via his email.

Richard Tomasso returned to the meeting at 10:03AM.

Mr. Tejero commented that the current USP interpretation may have additional safety measures for compounded, sterile products but believes that patient access to compounded medication will decrease.

Board discussion ensued.

Mr. Wuest will continue discussions and work on the language before bringing it back before the Board at a future meeting.

A. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment ensures proper and adequate safeguards for registered nurses who participate in certain public health programs or certain mental health services.

Dave Wuest presented background on the proposed agenda item.

President Park opened the floor to public comment.

There was no public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt proposed regulation Amendment to Nevada Administrative Code (NAC) 639 as presented by Mr. Wuest.

Second: Wayne Mitchell

Action: Passed unanimously.

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

A. Angeles Medical Supplies LLC – Las Vegas, NV

Rebekah Thompson (Administrator), Yaequeline Gonzalez-Villafuaneq (Owner), and Ivan Ortiz (Translator) appeared and were sworn in by President Park prior to answering questions and offering testimony.

Gus Vanderdonck, Associate General Counsel for the Nevada Board of Pharmacy, presented background on the application and questioned their business model and how they intend to get business.

Ms. Thompson and Ms. Gonzalez-Villafuaneq answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Medical, Devices, Equipment and Gases License for Angeles Medical Supplies LLC.

Second: Krystal Freitas

Action: Passed unanimously.

C. Kynetic Medical Group, Inc – Las Vegas, NV

Albert Marquez, Administrator, and Jeremie Ramirez ,Director of Operations, appeared and were sworn in by President Park.

Greg Zunino, Senior General Counsel for the Nevada Board of Pharmacy, presented background on the application and questioned their business model.

Mr. Marquez and Mr. Ramirez answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Medical, Devices, Equipment and Gases License for Kynetic Medical Group, Inc.

Second: Krystal Freitas

Action: Passed unanimously.

D. LifePro Medical Supplies – Las Vegas, NV

Andrea Aguilar, Owner and Administrator, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Greg Zunino presented background on the application and questioned the business model, the types of products she plans to sell, how she intends to get business, and her experience in the field.

Gener Tejero questioned Ms. Aguilar on how she was able to purchase the stock from a wholesaler without any registration.

Ms. Aguilar answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Nevada Medical, Devices, Equipment and Gases License for LifePro Medical Supplies, pending a favorable inspection.

Second: Gener Tejero

Action: Passed unanimously.

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

A. Pearl Surgery Center – North Las Vegas, NV

Sara Szabatura, Designated Representative, and Mary Grear, Pharmacist Consultant, appeared and were sworn in by President Park prior to answering questions and offering testimony.

Yenh Long, Deputy Director for the Nevada Board of Pharmacy, requested a Letter of Authorization for Ms. Szabatura and Ms. Grear to speak on behalf of the company.

Ms. Long presented background on the application and questioned their business model and how they intend to get business.

Ms. Szabatura and Ms. Grear answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Medical, Devices, Equipment and Gases License for Pearl Surgery Center.

Second: Jade Jacobo

Action: Passed unanimously.

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

C. Vegas Youn Pharmacy – Las Vegas, NV

Chang Kim, Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Yenh Long presented background on the application and questioned Mr. Kim on the business model and how he intends to solicit business.

Mr. Kim answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Nevada Pharmacy License for Vegas Youn Pharmacy.

Second: Jade Jacobo

Action: Passed unanimously.

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

A. Allaymeds Inc – San Antonio, TX

Suryanarayana Raju Sagi, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Joe Dodge presented background on the application and questioned Mr. Sagi's experience and the business model.

Mr. Dodge confirmed that Mr. Ragu will be only shipping two products into Nevada.

Mr. Ragu answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the Out-of-State Compounding Pharmacy for Allaymeds Inc.

Second: Krystal Freitas

Action: Passed unanimously.

B. Civic Center Pharmacy – Scottsdale, AZ

Tenille Davis, Managing Pharmacist, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Jade Jacobo disclosed that she knows Ms. Davis but can participate fairly and without bias.

Joe Dodge presented background on the application and questioned Ms. Davis on the change of ownership, name change, and the disclosures listed.

Ms. Davis answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Compounding Pharmacy for Civic Center Pharmacy.

Second: Wayne Mitchell

Action: Passed unanimously.

15. Request for a waiver from the Managing Pharmacist Pursuant to NRS 639.220 (3) – Appearance (**FOR POSSIBLE ACTION)**

A. J.T. Simonsen, B.S., Pharm.D

Joseph (J.T.) Simonsen appeared and was sworn in by President Park prior to answering questions and offering testimony.

Dave Wuest presented background on the appearance.

Mr. Simonsen provided a statement to the Board and will temporarily manage the secondary pharmacy until a second managing pharmacist is hired.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the waiver request from J.T. Simonsen to manage two pharmacies for Humboldt General Hospital.

Second: Jade Jacobo

Action: Passed unanimously.

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

    C. Strides Pharma, Inc – Chesnut Ridge, NY

Ken Waibel, Director of Manufacturing and Packaging, and Faiza Poshni, DEA Compliance and State Licensing Manager, appeared and were sworn by President Park prior to answering questions and offering testimony.

Gus Vanderdonck presented background on the application and questioned their business model and the products that will be manufactured.

Richard Tomasso was excused from the Board meeting at 1:33PM.

Mr. Vanderdonck requested clarification on the disclosure listed on the application and the FDA warning letter received from their parent company.

Ms. Poshni answered the questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Wholesaler License application for Strides Pharma, Inc.

Second: Gener Tejero

Action: Passed unanimously (Tomasso excused).

A. LifeScience Logistics, LLC – Durham, NC

Jeremy Bullock, Operations Manager, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gus Vanderdock requested a Letter of Authorization for Mr. Bullock to speak on behalf of the company.

Richard Tomasso returned to the Board meeting at 1:45PM.

Mr. Vanderdonck presented background on the application and questioned Mr. Bullock on the business model and disclosures listed on application.

Mr. Bullock answered the questions and commented that he is unfamiliar with the disclosures listed in other states as he started with the company in 2022 and the disclosures occurred prior to his employment.

Mr. Bullock stated that an updated application with his information was sent to the Board on September 1, 2023.

President Park tabled this application and will return to this matter.

B. Pharma Source Direct, Inc – Englewood, CO

Matthew Johnson, President and CEO, appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gus Vanderdonck presented background on the application and questioned Mr. Johnson on the business model and his disclosure.

Mr. Johnson answered the questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the ownership change on the Out-of-State Wholesaler License for Pharma Source Direct, Inc.

Second: Jade Jacobo

Action: Passed unanimously.

11. Application for Pharmacist Registration Renewal (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

A. Hai Duong Ngo

No representative was present on behalf of Hai Duong Ngo.

This matter was continued to a future Board meeting.

B. Roland Israel

No representative was present on behalf of Roland Israel.

This matter was continued to a future Board meeting.

C. Tony Hieu La

No representative was present on behalf of Tony Hieu La.

This matter was continued to a future Board meeting.

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

A. Chasity Beene

This matter was continued to a future Board meeting.

B. Jacob Hedden

Jacob Hedden appeared and was sworn in by President Park prior to answering questions and offering testimony.

Gus Vanderdonck presented background on the application and questioned Mr. Hedden on the disclosure related to a substance abuse disorder.

Mr. Hedden answered questions to the Board's satisfaction.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the application for Controlled Substance Registration for Jacob Hedden with the condition that he will continue PRN treatment in Nevada through December 2024.

Second: President Park

Action: Passed unanimously.

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

B. LifeScience Logistics, LLC – Durham, NC

President Park returned to LifeScience Logistics, LLC.

Gus Vanderdonck presented background on the application and questioned Mr. Bullock on the updated application and his experience.

Yenh Long questioned Mr. Bullock on how they will function as a 3PL for some manufacturers and where the manufacturers are located.

Mr. Bullock answered questions to the Board's satisfaction.

Board Action:

Motion: Jade Jacobo moved to approve the Out-of-State Wholesaler License for LifeScience Logistics, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

22. Public Comment January 18, 2024, 2:19PM

There was no public comment.

21. Date and Location of Next Scheduled Board Meeting:

March 6-7, 2024 – Las Vegas, NV

23. Adjournment

4

4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Pacific Medical, Inc. (Northern Nevada Sierra)

MDEG Physical Address: 6500 Longly Ln

City: Reno State: NV Zip: 89511

Mailing Address (if different from physical address): 1700 N. Chrisman Road

City: Tracy State: CA Zip: 95304

Telephone: 800 7269180 Website: www.pacmedical.com

Email: mweaver@pacmedical.com

Name of MDEG Administrator (NAC 639.694): Jennifer Wadhams

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☑ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☑ Practitioners[a]	☐ Life-sustaining equipment**
☑ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☑ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☑ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Jennifer Wadhams
	Telephone: 775-303-5277

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

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

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

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

Name: None Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California / Pacific Medical, Inc.

Parent Company (if any): _____

Corporation/Organization Name: Pacific Medical, Inc.

Mailing Address: 1700 N. Chrisman Road

City: Tracy State: CA Zip: 95304

Telephone: 800 726-9180 Email: mweaver@pacmedical.com

Contact Person Name: Mark Weaver

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

MARK WEAVER

Print Name of Authorized Person Submitting Application

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

1.22.2024

Date

Board Use Only	Date Received: 2/5/24	Amount: $500-Check 149336

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/14/2023

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

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

PRODUCER	CONTACT NAME: Josh Jones	
The Liberty Company Insurance Brokers Lic #0D79853 5955 De Soto Ave, Ste 250 Woodland Hills CA 91367	PHONE (A/C, No, Ext): (888) 918-3960	FAX (A/C, No):
	E-MAIL ADDRESS: jjones@libertycompany.com	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Pacific Medical, Inc. 1700 N. Chrisman Road Tracy CA 95304	INSURER A: Atlantic Specialty Insurance Company	
	INSURER B: Everest Premier Insurance Company	16045
	INSURER C: MedMarc Casualty Insurance Co	22241
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 23/24 COIs **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	☒ COMMERCIAL GENERAL LIABILITY ☐ CLAIMS-MADE ☒ OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: ☐ POLICY ☐ PRO-JECT ☒ LOC ☐ OTHER:	Y	Y	7110179130001	05/27/2023	05/27/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Stop Gap WY/WA	$ 1,000,000 $ 500,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ Excluded $ 500,000
A	AUTOMOBILE LIABILITY ☒ ANY AUTO ☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS ☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			7110179130001	05/27/2023	05/27/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Medical payments	$ 1,000,000 $ $ $ $ 5,000
A	☒ UMBRELLA LIAB ☒ OCCUR ☐ EXCESS LIAB ☐ CLAIMS-MADE ☐ DED ☒ RETENTION $ 10,000			7110179130001	05/27/2023	05/27/2024	EACH OCCURRENCE AGGREGATE 	$ 5,000,000 $ 5,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		CA10003843231	05/27/2023	05/27/2024	☒ PER STATUTE ☐ OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Products & Completed Ops Liability Professional Liability	Y		23CA380048	05/27/2023	05/27/2024	Aggregate Each Claim	$5,000,000 $5,000,000

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

RE: 961 Matley Lane, #160, Reno, Nevada 89502 Evidence of Coverage in Force.

CERTIFICATE HOLDER

NP West
PO Box 100142
Columbia SC 29202

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Josh Jones

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Pacific Medical, Inc.

Officer and Director list

Officers/Directors

John Petlansky – President/CEO

- 1700 N. Chrisman Road, Tracy, CA 95304
- jpetlansky@pacmedical.com

Jeffrey Leonard – Treasurer/CFO

- 1700 N. Chrisman Road, Tracy, CA 95304
- jleonard@pacmedical.com

Mark Weaver – General Counsel/CLO

- 1700 N. Chrisman Road, Tracy, CA 95304
- mweaver@pacmedical.com

State of California
Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME:

PACIFIC MEDICAL, INC.

FILE NUMBER:	C1848422
FORMATION DATE:	12/16/1992
TYPE:	DOMESTIC CORPORATION
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 19, 2017.

ALEX PADILLA
Secretary of State

RJB

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Pacific Medical, Inc. (Northern Nevada Sierra) MDEG License # (if applicable): _____

Physical Address: 6500 Longly Lane

City: Reno State: NV Zip: 89511

Mailing Address (if different from physical address): 1700 N. Chrisman Road.

City: Tracy . State: CA Zip: 95304

Telephone: 800 726-9180 Website: www.pacmedical.com

Licensing Company Email: mweaver@pacmedical.com

Section 2: Personal Information

First: Jennifer Middle: Lee Last: Wadhams

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

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

Mailing Address: [redacted]

City: Fallon State: NV Zip: 89406

Telephone: [redacted] Email: jwadhams@pacmedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		09/2001 - 05/2005	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Churchill County High School			
Address	**City**	**State**	**Zip**
1 Greenwave Circle	Fallon	NV	89406
Diploma/Degree obtained, if any			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/14 - current	[redacted]	Fallon	NV	89406
09/2013 - 09/2014	[redacted]	Fallon	NV	89406

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

Business Name			From - To (MM/YY – MM/YY)	
Pacific Medical, Inc.			09/2012 - Current	
Business Address		**City**	**State**	**Zip**
961 Matley Lane, Suite 160		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775 303 5277	Territory Manager		22,880	
Description of Duties				
*Provide exceptional customer service to all patients with products, services, billing, etc. *Surpervise/train/support team members to ensure proper patient services, products, sales ofa ll insurance billing activity.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1-23-24
Date

I, Jennifer Wadhams, **certify that as the MDEG Administrator for**

Pacific Medical, Inc.,

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

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

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

Jennifer Wadhams
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-23-24
Date

Board Use Only	Date Received: 2/5/24

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Pacific Medical, Inc. (Renown South Meadows)

MDEG Physical Address: 10101 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): 1700 N. Chrisman Road

City: Tracy State: CA Zip: 95304

Telephone: 800 7269180 Website: www.pacmedical.com

Email: mweaver@pacmedical.com

Name of MDEG Administrator (NAC 639.694): Jennifer Wadhams

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☑ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☑ Practitioners[a]	☐ Life-sustaining equipment**
☑ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☑ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☑ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Jennifer Wadhams
	Telephone: 775-303-5277

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

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

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

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

Name: None Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

   a) A practicing health professional; or

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California / Pacific Medical, Inc.

Parent Company (if any): _____

Corporation/Organization Name: Pacific Medical, Inc.

Mailing Address: 1700 N. Chrisman Road

City: Tracy State: CA Zip: 95304

Telephone: 800 726-9180 Email: mweaver@pacmedical.com

Contact Person Name: Mark Weaver

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Mark Weaver

Print Name of Authorized Person Submitting Application

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

1.22.2024

Date

Board Use Only	Date Received: 25124	Amount: $500 - check 198335

PacMed TIN	Office Name	ADDRESS	CITY	STATE	ZIP Plus 4	VENDOR_NPI	PTAN #	Services
943170060	Pacific Medical, Inc.	300 Providence Dr, Suite B112	Anchorage	AK	99508	1649687138		DME, Custom fit Orthotics
943170060	Pacific Medical, Inc.	1909 16th St, Suite 1	Bakersfield	CA	93301	1932791795		DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	6011 N Fresno Suite 115	Fresno	CA	93720	1881912566	695470012	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	609 E Orangeburg Avenue #102	Modesto	CA	95350	1386892529	695470003	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical, Inc.	1335 Coffee Road #210	Modesto	CA	95355	1356599591		DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	2201 Broadway, Suite 328	Oakland	CA	94612	1861809378		DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	1760 Gold St., Suite 400 & 500	Redding	CA	96001-1800	1811223647	695470005	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	1301 Secret Ravine Pkwy #100	Roseville	CA	95661	1265664023	695470006	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	2901 K St Ste 170	Sacramento	CA	95816-5123	1346947462	695470038	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	264 San Jose St., Suite A	Salinas	CA	93901	1811287337	695470007	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	500 Baker Street	San Francisco	CA	91199	1841553682	695470028	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	123 Di Salvo Ave, Suite 70	San Jose	CA	95128	1467727727	695470033	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
	Pacific Medical, Inc.	4554 Broad St.	San Luis Obispo	CA	93401-8712	1558778068		DME, Custom fit Orthotics
943170060	Pacific Medical Inc	5276 Hollister Ave.	Santa Barbara	CA	93111-2073	1366834509		DME, Custom fit Orthotics
943170060	Pacific Medical Inc	200 Montgomery Dr.	Santa Rosa	CA	95404-6633	1437566940		DME, Custom fit Orthotics
943170060	Pacific Medical Inc	1024 W. Robinhood Way	Stockton	CA	95207	1346735933	695470036	DME, Custom fit Orthotics
943170060	Pacific Medical Inc	1700 N Chrisman Road	Tracy	CA	95304	1326048893	695470001	DME, Custom fit Orthotics
943170060	Pacific Medical Inc	1851 E Paradise Road, Suite B	Tracy	CA	95304	1689954604		DME, Custom fit Orthotics
943170060	Pacific Medical Inc	190 N Wiget Lane, Suite 110	Walnut Creek	CA	94598	1760720965	695470026	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
	Pacific Medical Prosthetics & Ortho	901 N. Curtis Road, Suite 101 & 102	Boise	ID	83706	1548784036	695470035	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical, Inc.	2475 Village Lane, Suite 100	Billings	MT	59102	1497162911		DME, Custom fit Orthotics
943170060	Pacific Medical, Inc.	2740 South Ave. W, Suite 202	Missoula	MT	59804	1205126794	695470037	DME, Custom fit Orthotics
943170060	Pacific Medical, Inc.	123 W. Nye Lane, Ste 131	Carson City	NV	89706	1730596016		DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	961 Matley Lane, Suite 160	Reno	NV	89502	1891101051	695470027	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	2200 NE Neff Road #306	Bend	OR	97701	1326289315	695470017	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	2292 NW Kings Blvd	Corvallis	OR	97330	1801186390	695470021	DME, Custom fit Orthotics
943170060	Pacific Medical Inc	87 Centennial Loop	Eugene	OR	97401	1275940553	695470032	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	2594 E. Barnett Road, Suite A	Medford	OR	97504	1548573561	695470016	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Inc	2311 NW Northrup St., Suite 202	Portland	OR	97210	1801203187	695470029	DME, Custom fit Orthotics
943170060	Pacific Medical, Inc.	3120 Squalicum Pkwy, Suite 1	Bellingham	WA	98225-1934	1093122350		DME, Custom fit Orthotics
943170060	Pacific Medical, Inc.	275 SW 160th St., Suite 110	Burien	WA	98166	1114661253	695470037	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	7308 Bridgeport Way W #204	Lakewood	WA	98499	1316188303	695470015	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	350 South 38th Court, #110	Renton	WA	98055	1568766343	695470020	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	969 Stevens Drive, Suite 2A & 2C	Richland	WA	99352	1164654935	695470022	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Inc	611 E 2nd Ave	Spokane	WA	99212	1760984132	695470034	DME, Custom fit Orthotics
943170060	Pacific Medical Prosthetics & Ortho	1724 West Union Ave, Suite 202	Tacoma	WA	98405	1073808184	695470019	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics
943170060	Pacific Medical Prosthetics & Ortho	317 S 11th Avenue	Yakima	WA	98902	1730492653	695470025	DME, Custom fit Orthotics, Custom Orthotics, Prosthetics

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ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/14/2023

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

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

PRODUCER	CONTACT NAME: Josh Jones
The Liberty Company Insurance Brokers Lic #0D79653 5955 De Soto Ave, Ste 250 Woodland Hills CA 91367	PHONE (A/C, No, Ext): (888) 918-3960 FAX (A/C, No): E-MAIL ADDRESS: jjones@libertycompany.com

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Pacific Medical, Inc. 1700 N. Chrisman Road Tracy CA 95304	INSURER A: Atlantic Specialty Insurance Company	
	INSURER B: Everest Premier Insurance Company	16045
	INSURER C: MedMarc Casualty Insurance Co	22241
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 23/24 COIs **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [ ] POLICY [ ] PRO-JECT [X] LOC [ ] OTHER:	Y	Y	7110179130001	05/27/2023	05/27/2024	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 500,000
							MED EXP (Any one person)	$ 15,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
							Stop Gap WY/WA	$ 500,000
A	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			7110179130001	05/27/2023	05/27/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
							Medical payments	$ 5,000
A	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [X] RETENTION $ 10,000			7110179130001	05/27/2023	05/27/2024	EACH OCCURRENCE	$ 5,000,000
							AGGREGATE	$ 5,000,000
								$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		CA10003843231	05/27/2023	05/27/2024	[X] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Products & Completed Ops Liability Professional Liability	Y		23CA380048	05/27/2023	05/27/2024	Aggregate Each Claim	$5,000,000 $5,000,000

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

RE: 961 Matley Lane, #160, Reno, Nevada 89502 Evidence of Coverage in Force.

CERTIFICATE HOLDER

NP West
PO Box 100142
Columbia SC 29202

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Josh Jones

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The ACORD name and logo are registered marks of ACORD

Pacific Medical, Inc.

Officer and Director list

Officers/Directors

John Petlansky – President/CEO

- 1700 N. Chrisman Road, Tracy, CA 95304
- jpetlansky@pacmedical.com

Jeffrey Leonard – Treasurer/CFO

- 1700 N. Chrisman Road, Tracy, CA 95304
- jleonard@pacmedical.com

Mark Weaver – General Counsel/CLO

- 1700 N. Chrisman Road, Tracy, CA 95304
- mweaver@pacmedical.com

State of California
Secretary of State

CERTIFICATE OF STATUS

ENTITY NAME:

PACIFIC MEDICAL, INC.

FILE NUMBER:	C1848422
FORMATION DATE:	12/16/1992
TYPE:	DOMESTIC CORPORATION
JURISDICTION:	CALIFORNIA
STATUS:	ACTIVE (GOOD STANDING)

I, ALEX PADILLA, Secretary of State of the State of California, hereby certify:

The records of this office indicate the entity is authorized to exercise all of its powers, rights and privileges in the State of California.

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 19, 2017.

ALEX PADILLA
Secretary of State

RJB

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Pacific Medical, Inc. (Renown South Meadows) MDEG License # (if applicable): _____

Physical Address: 10101 Double R Blvd

City: Reno State: NV Zip: 89521

Mailing Address (if different from physical address): 1700 N. Chrisman Road

City: Tracy State: CA Zip: 95304

Telephone: 800 726-9180 Website: www.pacmedical.com

Licensing Company Email: mweaver@pacmedical.com

Section 2: Personal Information

First: Jennifer Middle: Lee Last: Wadhams

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

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

Mailing Address: [redacted]

City: Fallon State: NV Zip: 89406

Telephone: [redacted] Email: jwadhams@pacmedical.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		09/2001 - 05/2005	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Churchill County High School			
Address	**City**	**State**	**Zip**
1 Greenwave Circle	Fallon	NV	89406
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/14 - current	[redacted]	Fallon	NV	89406
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2013 - 09/2014	[redacted]	Fallon	NV	89406
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Pacific Medical, Inc.			09/2012 - Current	
Business Address		**City**	**State**	**Zip**
961 Matley Lane, Suite 160		Reno	NV	89502
Phone	**Title**		**Number of Employed Hours**	
775 303 5277	Territory Manager		22,880	
Description of Duties				
*Provide exceptional customer service to all patients with products, services, billing, etc. *Surpervise/train/support team members to ensure proper patient services, products, sales ofa ll insurance billing activity.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1-23-21
Date

I, Jennifer Wadhams **, certify that as the MDEG Administrator for**

Pacific Medical, Inc.,

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

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

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

Jennifer Wadhams
Print Name (First, Last)

Jennifer Wadhams
Original Signature (electronic, copies or stamps not accepted)

1-23-24
Date

Board Use Only	Date Received: 2/5/24

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG	* If making a change, provide current license number:	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
■ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*	M P00799	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*		☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Vantive US Healthcare LLC

MDEG Physical Address: 7511 114th Avenue North

City: Largo State: FL Zip: 33773

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip: 43017

Telephone: (727) 541-6411 Website:

Email: licensure@cardinalhealth.con

Name of MDEG Administrator (NAC 639.694): David Wheeler

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 7am - 12am	■ Tue: 7am - 12am	■ Wed: 7am - 12am	■ Thurs: 7am - 12am	■ Fri: 7am - 12am
☐ Sat: CLOSED	☐ Sun: CLOSED	☐ Holidays: CLOSED		

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

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

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

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Baxter Healthcare Corporation

Corporation Name: Vantive US Healthcare LLC

Mailing Address: One Baxter Parkway

City: Deerfield State: IL Zip: 60015

Telephone: 224-948-2000 Email: licensure@cardinalhealth.com

Contact Person Name: Chauna Mason

Date of SEC Registration: 10/19/1931	SEC Registration Number: 0000010456	Stock Exchange Symbol: BAX

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

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

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

LaToyia M. Martin

Print Name of Authorized Person Submitting Application

LaToyia M. Martin

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

12/21/2023

Date

Board Use Only	Date Received: 12/28/23	Amount: $500 cc

MEMORANDUM OF LIABILITY INSURANCE	Date Sept 1, 2023

This Memorandum is issued as a matter of information only to authorized viewers for their internal use and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed, and distributed by an authorized viewer and may only be used by an authorized viewer for internal use. Any other use, duplication or distribution of this Memorandum without prior written consent of Baxter Risk Management is prohibited. This memorandum does not constitute a contract between authorized viewer and the issuing Insurer(s) or Baxter. Neither the Insured nor the producer shall have the obligation to inform an authorized viewer of any changes to this information. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://connect.baxter.com/sites/functions/RiskMngmt/Pages/Certificates-of-Insurance.aspx.
The information contained herein is as of the date referred above.

INSURED
Baxter International, Inc. and
All Affiliates, Divisions and Subsidiaries thereof including
Baxter Healthcare Corporation and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield, IL 60015 USA

INSURER(S) AFFORDING COVERAGE	NAIC#
A: Old Republic Insurance Company	24147
B: Illinois Union Insurance Company	27960
C: Steadfast Insurance Company	26387
D:	
E:	
F:	

COVERAGES

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

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE (MM/DD/YYYY)	POLICY EXPIRATION (MM/DD/YYYY)	LIMITS (USD)	
A	**COMMERCIAL GENERAL LIABILITY**	MWZY 57820 23	9/1/2023	9/1/2024	EACH OCCURRENCE	$2,000,000
					DAMAGE TO RENTED PREMISES	$50,000
					MED EXPENSE	$25,000
					PERSONAL & ADV INJURY	$2,000,000
					GENERAL AGGREGATE	$4,000,000
					PRODUCTS – COMP/OP AGG	Excluded
A	**AUTOMOBILE LIABILITY**	MWTB 20158 23	9/1/2023	9/1/2024	COMBINED SINGLE LIMIT	$5,000,000
B	**UMBRELLA LIABILITY**	XEUG27981604 008	9/1/2023	9/1/2024	EACH OCCURRENCE	$3,000,000
					AGGREGATE	$3,000,000
A	**WORKERS COMPENSATION AND EMPLOYER'S LIABILITY** Any Proprietor / Partner / Executive Officer / Member Excluded? **N**	MWC11550216 (All Other States)	9/1/2023	9/1/2024	PER STATUTE	
					E.L. EACH ACCIDENT	$2,000,000
A		MWXS82923 (Excess IL)	9/1/2023	9/1/2024	E.L. DISEASE EA EMPLOYEE	$2,000,000
					E.L. DISEASE POLICY LIMIT	$2,000,000
A	**PRODUCT LIABILITY**	MWZY 31692223	9/1/2023	9/1/2024	EACH CLAIM	$5,000,000
					AGGREGATE	$5,000,000
C	**CYBER LIABILITY** **Network and Security**	SPR 0142190-06	5/1/2023	5/1/2024	LIMIT	$5,000,000

ADDITIONAL INFORMATION

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

Vantive US Healthcare LLC
Corporate Officers

Name	Title
Michael A. Cascella, Jr.	Vice President, Tax
Matthew Koller Harbaugh	VP, Finance
Karen L. Leets	Vice President and Treasurer
James William Borzi	SVP, Chief Supply Chain Officer
Ellen K. Bradford	SVP and Corporate Secretary

Sunbiz.org DIVISION of CORPORATIONS
an official State of Florida website

Detail by Entity Name

Foreign Limited Liability Company
VANTIVE US HEALTHCARE LLC

Filing Information

Document Number	M23000014093
FEI/EIN Number	93-3828311
Date Filed	11/02/2023
State	DE
Status	ACTIVE
Last Event	LC AMENDMENT
Event Date Filed	11/29/2023
Event Effective Date	NONE

Principal Address

ONE BAXTER PKWY.
DEERFIELD, IL 60015

Mailing Address

ONE BAXTER PKWY.
DEERFIELD, IL 60015

Registered Agent Name & Address

C T CORPORATION SYSTEM
1200 SOUTH PINE ISLAND ROAD
PLANTATION, FL 33324

Authorized Person(s) Detail

Name & Address

Title VP/S

BRADFORD, ELLEN K
ONE BAXTER PKWY.
DEERFIELD, IL 60015

Title VP/T

LEETS, KAREN L
ONE BAXTER PKWY.
DEERFIELD, IL 60015

Title VP

BORZI, JAMES
ONE BAXTER PKWY.
DEERFIELD, IL 60015

Title VP

CASCELLA, MICHAEL A, JR.
ONE BAXTER PKWY.
DEERFIELD, IL 60015

Title VP

HARBAUGH, MATTHEW T
ONE BAXTER PKWY.
DEERFIELD, IL 60015

Annual Reports

No Annual Reports Filed

Document Images

11/29/2023 -- LC Amendment	View Image in PDF format
11/02/2023 -- Foreign Limited	View Image in PDF format

VANTIVE US HEALTHCARE LLC

POWER OF ATTORNEY

As contemplated by the resolutions adopted by the Board of Directors of Vantive US Healthcare LLC, a Delaware limited liability corporation ("the Corporation"), effective October 20, 2023 ("Resolutions"), a copy of such Resolutions is attached hereto as Exhibit A, the undersigned Matthew Rice, Assistant Secretary, an Authorized Representative of Vantive US Healthcare LLC, hereby delegates to Keegan Chamberlain, Director of Quality Management and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of Vantive US Healthcare LLC.

This power of attorney shall be effective until December 31, 2024 and is subject to revocation by any officer of Vantive US Healthcare LLC at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: October ___, 2023

Vantive US Healthcare LLC

Matthew Rice
Assistant Secretary
Authorized Representative

EXHIBIT A

VANTIVE US HEALTHCARE LLC
MISCELLANEOUS RESOLUTIONS
Adopted October 20, 2023

VANTIVE US HEALTHCARE LLC

WRITTEN CONSENT
OF THE MANAGERS

Effective as of October 20, 2023 ("Effective Date")

THE UNDERSIGNED, being all of the managers (the "Managers") of Vantive US Healthcare LLC, a Delaware limited liability company (the "Company"), do hereby, pursuant to the provisions of Section 18-404 of the Delaware Limited Liability Company Act, approve, adopt, consent to and vote for the following actions and resolutions and each and every action effected thereby:

APPROVAL OF THE FORMATION AND FORMATION ACTIONS

****

MISCELLANEOUS

RESOLVED, that any Manager or officer of the Company, or such other individuals that the Company shall, by power of attorney or otherwise, determine to be necessary, appropriate or advisable (together, the "Authorized Representatives" and each, an "Authorized Representative"), be and each hereby is authorized, empowered and directed, acting jointly with one or more other Authorized Representatives, to do or cause to be done all things and acts, to negotiate, approve, execute, acknowledge, sign, deliver, file and perform or cause to be negotiated, approved, executed, acknowledged, signed, delivered, filed and performed on behalf of the Company any such agreements, instruments or other documents, make all filings, issue powers of attorney, and otherwise take any further action, which in the judgment of the Authorized Representatives are necessary, appropriate or advisable to consummate the foregoing resolutions and perform its obligations thereunder and otherwise to carry out and comply with the intent and purposes of the resolutions herein;

FURTHER RESOLVED, that all of the past acts and transactions of any Authorized Representative (or other representative or agent of the Company), including, but not limited to, preparation, execution, deliveries and filings of agreements, instruments, certificates and other documents in the name of and on behalf of the Company or any of its affiliates, and all fees and expenses (including taxes) incurred or paid by any Authorized Representative (or other representative or agent of the Company) having been deemed necessary, proper or advisable to carry out the intent and effectuate the purposes hereof, prior to the execution of these resolutions, taken in good faith in the name and on behalf of the Company or any of its affiliates pursuant to and consistent with the resolutions contained herein, be and hereby are consented to, adopted, authorized, approved, confirmed and ratified in all respects; and

FURTHER RESOLVED, that these resolutions may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts

IN WITNESS WHEREOF, the undersigned have duly executed this Written Consent effective as of the Effective Date.

Christopher Toth, Manager

David S. Rosenbloom, Manager

Joel T. Grade, Manager

412992826

(Signature page to Manager Resolutions of Vantive US Healthcare LLC)

Vantive US Healthcare, LLC Disclosures

There are no relevant disciplinary actions taken against the applicant corporation Vantive US Healthcare, LLC ("Vantive US") or the facility related to the license. Vantive US is a subsidiary of Baxter Healthcare Corporation, which in turn is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange with tens of thousands of employees world-wide. For purposes of transparency, we are providing disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation. Additional information regarding specific Vantive US or Baxter Healthcare Corporation facilities (e.g., inspection history) can be found on the FDA website.

State Pharmacy License Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling,

and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities.

Iowa, Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third party logistics provider. Inspectors concluded Baxter (Round Lake, IL) violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor – health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved this matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Officer Disclosure

The Vice President and Secretary of Baxter Healthcare Corporation had a misdemeanor DUI conviction in December 2000, in Austin, Texas.

DIVISION OF DRUGS, DEVICES AND COSMETICS – FAQS

Drugs, Devices & Cosmetics FAQs

To obtain an interpretation of statute or rule from an agency requires the submission of a Petition for Declaratory Statement that is authorized by Chapter 120, Florida Statutes and an agency cannot provide an informal legal opinion. The responses to the frequently asked questions are not intended to be legal opinions or statements of agency policy and you are strongly encouraged to seek the guidance of a regulatory consultant to assist you regarding the interpretation and application of Florida Statutes and rules.

Definitions:

- "DBPR" or the "department" or refers to the Florida Department of Business and Professional Regulation.
- "DEA" refers to the U.S. Drug Enforcement Administration.
- "ARCOS" refers to the Automation of Reports and Consolidated Orders System operated by DEA.
- "CSR" refers to Florida's state analogue to ARCOS, the Controlled Substance Reporting system.
- "E-FORCSE (https://florida.pmpaware.net/login)" refers to Florida's "Electronic-Florida Online Reporting of Controlled Substances Evaluation", aka the "Prescription Drug Monitoring Program" or "PDMP". For more information visit the E-FORCSE homepage at https://www.floridahealth.gov/statistics-and-data/e-forcse

/index.html (https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html).

- FTP - File Transfer Protocol

(http://www.myfloridalicense.com/DBPR/)

Division of Drugs, Devices and Cosmetics

Does my company need a permit?

DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories:(a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?
Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No
Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a "drug", "device", or "cosmetic"?

Refer to Section 499.003, Florida Statutes: http://www.leg.state.fl.us/statutes /index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections /0499.003.html (http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute& Search_String=&URL=0400-0499/0499/Sections/0499.003.html) Please note that "drug"

Select Year: 2023 Go

The 2023 Florida Statutes

Title XXXIII
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS

Chapter 499
FLORIDA DRUG AND COSMETIC ACT

View Entire Chapter

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or device to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must

notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21; s. 36, ch. 2014-89; s. 10, ch. 2016-212; s. 33, ch. 2017-3; s. 1, ch. 2017-51; s. 8, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 8, ch. 2019-99, amends subsection (1), to read:

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

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0097
Vantive US Healthcare LLC

1 Baxter Parkway, Building 6
Deerfield IL
1-800-333-0887

December 27, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno, NV, 89521

RE: Licensing activity related to Baxter Healthcare and the legal separation of its Kidney Care business, resulting in the attached Vantive US Healthcare LLC Medical Devices License Application

To Whom It May Concern:

This letter is intended to provide you with supporting background information for the attached Medical Devices for Vantive US Healthcare LLC.

In early 2023, Baxter International Inc. publicly announced the intention to separate its Kidney Care (renal and acute therapies) business into a new, independent, publicly traded company– the name of this new company is Vantive. The final separation is planned for mid-year 2024, subject to customary closing conditions and receipt of regulatory approvals.

A new legal entity, Vantive US Healthcare LLC, has been formed as a first step in the legal separation. Vantive US Healthcare LLC is currently a subsidiary of Baxter Healthcare Corporation, which is a subsidiary of Baxter International, Inc.. Vantive US Healthcare LLC will remain an indirect subsidary of Baxter International, Inc. until the final separation of the two companies mid year 2024. However, prior to that final separation and starting on February 1, 2024, sales for the Kidney Care products will be through Vantive US Healthcare LLC.[1]

Baxter Healthcare Corporation currently sells these theraputic products, which are used in the treament of end stage kidney disease, directly to patients at home. For this reason Baxter Healthcare Corporation is currently licensed in your state as a Medical Devices MP00799. The activities of Vantive US Healthcare LLC will be no different than those currently occurring with the existing Baxter Healthcare Corporation Medical Devices, therefore there should be no distinction between the existing Baxter Healthcare Corporation license and the attached application for Vantive US Healthcare, LLC.

We are providing this notification as we are requesting assistance by the state to ensure issuance of the attached license prior to February 1, 2024 in order to guarantee continuity of product supply to patients. Please contact me if there are any additional questions or concerns.

Sincerely,

LaToyia M. Martin
Manager, Quality Compliance

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Vantive US Healthcare LLC — MDEG License # (if applicable): _____

Physical Address: 7511 114th Avenue North

City: Largo — State: FL — Zip: 33773

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin — State: OH — Zip: 43017

Telephone: (727) 541-6411 — Website: _____

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: David — Middle: Kenneth — Last: Wheeler

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

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

Mailing Address: [redacted] Sandy Brook Cir

City: [redacted] Wimauma — State: FL — Zip: ~~33708~~ 33598

Telephone: [redacted] — Email: david_wheeler@baxter.com

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

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

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

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

School Name: Elmira College		From - To (MM/YY – MM/YY): 1982 - 1984	
Address: 1 Park Place	City: Elmira	State: NY	Zip: 14901
Diploma/Degree obtained, if any: B.S. Accounting			
School Name: Corning Community College		From - To (MM/YY – MM/YY): 1980 - 1982	
Address: 1 Academic Dr.	City: Corning	State: NY	Zip: 14830
Diploma/Degree obtained, if any: AAS General Studies			
School Name: Corning Painted Post East High School		From - To (MM/YY – MM/YY): 1972 1976	
Address: 201 Cantigny St.	City: Corning	State: NY	Zip: 14830
Diploma/Degree obtained, if any: High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2023 - present	[redacted] Sandy Brook Cir	Wimauma	FL	33598
06/2013 to 09/2023	[redacted] 173rd Ave[redacted]	North Redington Bch	FL	33708
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

School Name			From - To (MM/YY – MM/YY)	
Elmira College			1982 - 1984	
Address		City	State	Zip
1 Park Place		Elmira	NY	14901
Diploma/Degree obtained, if any				
B.S. Accounting				

School Name			From - To (MM/YY – MM/YY)	
Corning Community College			1980 - 1982	
Address		City	State	Zip
1 Academic Dr.		Corning	NY	14830
Diploma/Degree obtained, if any				
AAS General Studies				

School Name			From - To (MM/YY – MM/YY)	
Corning Painted Post East High School			1972	1976
Address		City	State	Zip
201 Cantigny St.		Corning	NY	14830
Diploma/Degree obtained, if any				
High School Diploma				

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name: Baxter Health Care Corp			From - To (MM/YY – MM/YY): 10/2017 – Present
Business Address: 7511 114th Ave	City: Largo	State: FL	Zip: 33773
Phone: 727-548-2123	Title: Associate Director		Number of Employed Hours: 12,480
Description of Duties: Facility ~~Manager~~ Manager – Servicing of medical devices and distribution of medical devices			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, David Wheeler, **certify that as the MDEG Administrator for**

Vantive US Healthcare LLC,

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

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

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

David Wheeler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/16/2023

Date

Board Use Only	Date Received: 12/08/23

4D

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: ALOM Technologies Corporation

Physical Address: 3910 Waldemere Ave

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 48021 Warm Springs Blvd

City: Fremont State: CA Zip: 94539

Telephone: (510) 360-3600 Website: https://alom.com/

Name of Designated Representative (DR): Rebecca Everett

Licensing Company Email: regulatory@alom.com DR Email: reverett@alom.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Maintained (✓ all applicable)	Type of Wholesaler (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Third-Party Logistics (3PL)

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

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

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

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

Provide explanation below:
N/A

Original Signature (electronic, copies or stamps not accepted)

8/29/2023
Date

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

Name: Calitho
Address: 2312 Stanwell Drive City: Concord State: CA Zip: 94520
Name: Miles Printing
Address: 4923 West 78th Street City: Indianapolis State: IN Zip: 46248
Name: Matrix Label
Address: 4692 S County Road 600 E City: Plainfield State: IN Zip: 46168
Name: Uline
Address: 12575 Uline Drive City: Pleasant Prairie State: WI Zip: 53158

Section 4: Publicly Traded Corporation

State of Incorporation: California
Parent Company (if any): N/A
Corporation Name: ALOM Technologies Corporation
Mailing Address: 48021 Warm Springs Blvd.
City: Fremont State: CA Zip: 94539
Telephone: (510) 360-3641 Email: regulatory@alom.com
Contact Person Name: Kaveh Moraghebi

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

Section 5: Non-Publicly Traded Corporation or Company

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

Section 6: Partnership

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

Section 7: Sole Owner

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

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at**: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

ALOM Technologies Corporation

Facility Name

Kaveh Moraghebi

Print Name of Authorized Person Submitting Application

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

8,29,2023

Date

Board Use Only	Date Received: 8/31/23	Amount: 1000-CK-83577

FDA U.S. FOOD & DRUG ADMINISTRATION

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ALOM Technologies Corporation
3910 Waldemere Avenue
Indianapolis, IN 46241
Registration Number: 3015489159
FEI Number*: 3015489159
Status: Active
Date Of Registration Status: 2023

Owner/Operator:

ALOM TECHNOLOGIES CORPORATION[6]
48021 WARM SPRINGS BLVD.
Fremont, CA US 94539

Owner/Operator Number: 9063998[7]

Official Correspondent:
Hannah Kain
48021 WARM SPRINGS BLVD.
Fremont, CA 94539
Phone: 510-3603636

Verified 9/14/23

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNu
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNu

ALOM

48021 Warm Springs Blvd.
Fremont, CA 94539-7498, U.S.A.
Main: 510.360.3600
Toll Free: 800.500.9991
Fax: 510.226.7617
www.alom.com

List of Officers/Directors

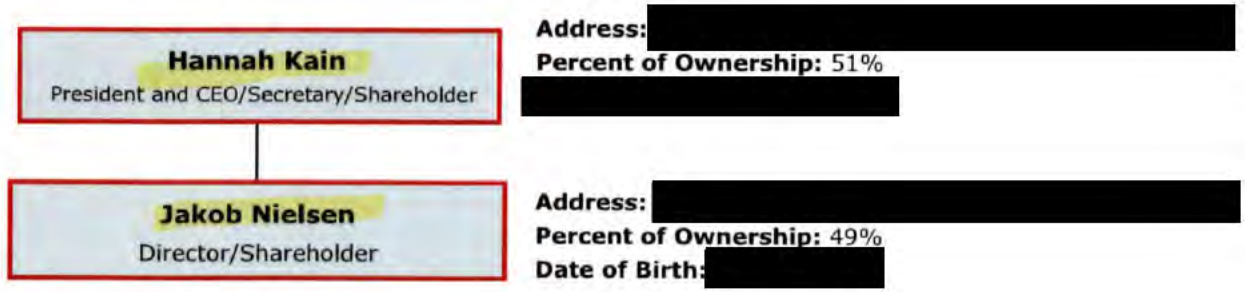
Hannah Kain
Title: President & CEO / Secretary / Shareholder
Home Address: [redacted]

Jakob Nielsen
Title: Shareholder / Director
Home Address: [redacted]

John Sexton
Title: Chief Financial Officer
Home Address: [redacted]

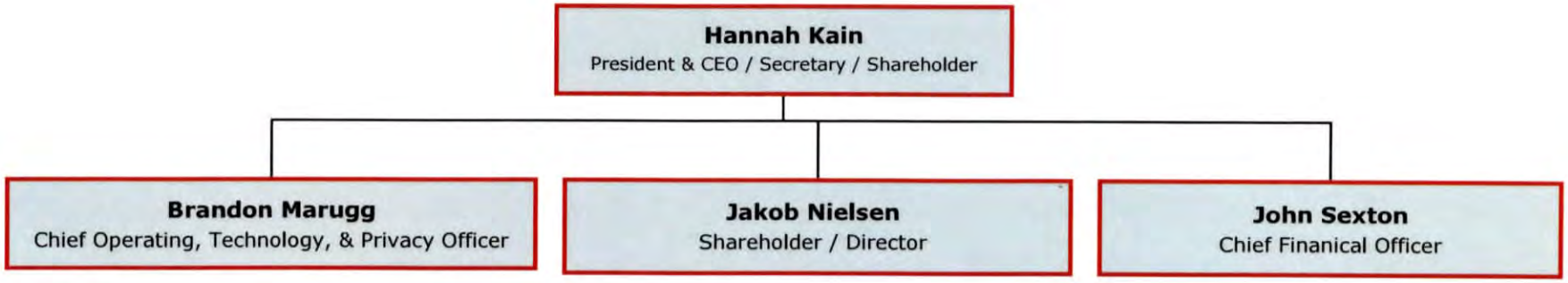
Brandon Marugg
Title: Chief Operating, Technology, & Privacy Officer
Home Address: [redacted]

ALOM Management - Ownership
2023



ALOM

Senior Management
2023



Secretary of State
Certificate of Status

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

Entity Name:	ALOM TECHNOLOGIES CORPORATION
Entity No.:	2012931
Registration Date:	06/06/1997
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

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

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

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 12, 2023.

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

Certificate No.: 073140014

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

DocuSign Envelope ID: 8F54668E-4BD5-42F1-A03F-318F4A7A40EC

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

Third Party Logistics Provider

License Number	Expire Date
94000202A	09/30/2024

ALOM Technologies Corp

Eric J. Holcomb
Governor
State of Indiana

Deborah J. Frye
Executive Director
Indiana Professional Licensing Agency

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

Third Party Logistics Provider

License Number	Expire Date
94000202A	09/30/2024

ALOM Technologies Corp

Signature DocuSigned by: Kaveh Moraghebi
173F421FA1B2437

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Digitally Certified Proof of Licensure

RE: ALOM Technologies Corp

I, Deborah J. Frye, Executive Director of the Indiana Professional Licensing Agency and custodian of the records therein, hereby certify that the attached is the digitally certified proof of licensure, as requested, and as it appears in the files of the Indiana Professional Licensing Agency on the date/time certified.

This digital certification follows the requirements of Indiana's Electronic Digital Signature Act (Indiana Code 5-24-1-1 et seq.) and rules developed by the Indiana State Board of Accounts, 20 IAC 3-1 et seq. to establish a valid digital electronic signature.

To verify the authenticity of the digital certification as of the date and time stamp below, go to
https://secure.in.gov/apps/pla/search/verify/
and use our free web service. Simply browse to the location you saved the secure PDF document sent to you and upload to validate. You may also verify the authenticity in Adobe by ensuring the 'Certified by State of Indiana' blue ribbon displays at the top of the PDF.

Deborah J. Frye

Deborah J. Frye, Executive Director
Fri Sep 16 07:55:49 PM EST 2022

STATE OF INDIANA

Eric J. Holcomb

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2960
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information

Facility Name:	ALOM Technologies Corp
Address:	3910 Waldemere Ave Indianapolis, IN 46241
Owner Name:	

License Information

Number Issued:	94000202A
License Type:	Third Party Logistics Provider
Status:	Active
Issue date:	02/28/2022
Expiration Date:	09/30/2024
Obtained By:	Application

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For disciplinary action information, please visit our License Search & Verify service at www.in.gov/pla/3119.htm. Disciplinary action will either show under Previous Action or Violations. For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at http://www.in.gov/pla/boards.htm.

Digitally Certified on: Fri Sep 16 07:55:49 PM EST 2022

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/12/2023

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

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

PRODUCER
(SM) Heffernan Insurance Brokers
1820 Gateway Drive, Suite 330
San Mateo CA 94404

License#: 0564249

CONTACT NAME:
PHONE (A/C, No, Ext): 650-842-5200 **FAX (A/C, No):** 650-842-5201
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Travelers Property Casualty Company of America	25674
INSURER C : Liberty Mutual Fire Insurance Company	23035
INSURER D : Houston Casualty Company	42374
INSURER E : Palomar Excess and Surplus Insurance Company	16754
INSURER F :	

INSURED
ALOM Technologies Corporation
48105 Warm Springs Blvd
Fremont CA 94539-7498

ALOMTEC-03

COVERAGES **CERTIFICATE NUMBER:** 1074684775 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			35360129	7/1/2023	7/1/2024	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	$ 2,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			73228075	7/1/2023	7/1/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			79766137	7/1/2023	7/1/2024	EACH OCCURRENCE	$ 20,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 20,000,000
	DED X RETENTION $ 0							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N	N / A		WC2Z91469215013	7/1/2023	7/1/2024	X PER STATUTE / OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
B	Excess Umbrella			EX3T99544723NF	7/1/2023	7/1/2024	Each Occ/Agg	5,000,000
D	Cyber/ Tech			H23NGP21834101	7/1/2023	7/1/2024	$100K Retention/Limit	5,000,000
E	Professional Liability			CPPLMEO22002201	7/1/2023	7/1/2024	$100K Retention/Agg	5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Professional Liability $250,000 Retention/ Per Claim/Aggregate $100,000
Excess Professional Liability - Homesite Insurance Policy#EEO02133200 Eff. 7/1/23-7/1/24 - Per Claim/Aggregate $5,000,000
Proof of Insurance

CERTIFICATE HOLDER

ALOM Technologies Corporation
48105 Warm Springs Blvd
Fremont CA 94539

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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MERCHANTS BONDING COMPANY™
MERCHANTS BONDING COMPANY (MUTUAL) P.O. BOX 14498, DES MOINES, IA 50306-3498
PHONE: (800) 678-8171 FAX: (515) 243-3854

ENDORSEMENT

It is hereby understood and agreed that Bond No.: NV5924068

Principal: ALOM Technologies Corporation dba ALOM,

Obligee: State of Nevada and Nevada State Board of Pharmacy

in the Merchants Bonding Company (Mutual), is changing this bond effective April 13, 2023

FROM:
Service address: 48105 Warm Springs Blvd. Fremont, CA 94539

TO:
Service address: 48105 Warm Springs Blvd. Fremont, CA 94539 and 3910 Waldemere Ave. Indianapolis, IN 46241

All terms and conditions of said bond, except as above changed, to remain the same.

Signed, sealed and dated this 24th day of April, 2023

Merchants Bonding Company (Mutual)

By Larry Taylor
Larry Taylor, President

SUP 0018 (2/15)

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Stephanie Worden

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

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 26th day of April , 2022 .

MERCHANTS NATIONAL BONDING, INC. -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 26th day of April , 2022 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

POLLY MASON
Commission Number 750576
My Commission Expires
January 07, 2023

Polly Mason
Notary Public

(Expiration of notary's commission
does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 26th day of April , 2022 .

MERCHANTS NATIONAL BONDING, INC. -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

NEVADA STATE BOARD OF PHARMACY

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

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. NV5924068

Application/License No. NRS 639.515.

ALOM Technologies Corporation dba ALOM (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 48105 Warm Springs Blvd. Fremont, CA 94539 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 26, 2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 26th day of April, 20 22.

APPLICANT/PRINCIPAL	SURETY
COMPANY	
ALOM Technologies Corporation dba ALOM	Merchants Bonding Company (Mutual)
Authorized Representative	Surety Company's Representative
Jack Sexton	Stephanie Worden, Attorney-in-fact print name
SIGNED and SEALED in the presence of:	SIGNED and SEALED in the presence of:
Witness	Witness
Witness	Witness
	Countersigned by:
	Nevada Resident Agent

LP 2079 NV (5/21)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: ALOM Technologies Corporation MDEG License # (if applicable): _____

Physical Address: 3910 Waldemere Ave

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 48021 Warm Springs Blvd

City: Fremont State: CA Zip: 94539

Telephone: (510) 360-3600 Website: https://alom.com/

Licensing Company Email: regulatory@alom.com

Section 2: Personal Information

First: Rebecca Middle: Ann Last: Everett

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

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

Mailing Address: [redacted]

City: Indianapolis State: IN Zip: 46241

Telephone: [redacted] Email: reverett@alom.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Indiana University - Purude University Indianapolis		01/1992 -01/1993	
Address	City	State	Zip
420 University Blvd	Indianapolis	IN	46202
Diploma/Degree obtained, if any			
Associates in Computer IT, Legal Environment Business Environment			
School Name		From - To (MM/YY – MM/YY)	
Indiana Business College (Harisson College)		02/1991 - 11/1991	
Address	City	State	Zip
550 E Washington St	Indianapolis	IN	46204
Diploma/Degree obtained, if any			
Associates in Communication/Business Management			
School Name		From - To (MM/YY – MM/YY)	
Pharmacy Trade School - Walmart/Hawkins		1980-1987	
Address	City	State	Zip
1002 W Taft Road	Sapulpa	Ok	74066
Diploma/Degree obtained, if any			
On the job training by 3 Licensed Pharmacist			
School Name		From - To (MM/YY – MM/YY)	
Arsenal Tech HS		1983 ? 1986 ?	
Address	City	State	Zip
1500 E. Michigan Street	Indianapolis	In	46202
Diploma/Degree obtained, if any			
12th GED			
School Name		From - To (MM/YY – MM/YY	
Sperry High School		1978 - 1980	
Address	City	State	Zip
400 W. Main Street	Sperry	OK	74073
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2020 -current	[redacted]	Plainfield	In	46168
09/1997 - 04/2020		Monrovia	In	46157
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

NA
DE
25 Aug 2023

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

Business Name			From - To (MM/YY – MM/YY)	
ALOM Technologies Corporation			05/23 - Present	
Business Address		City	State	Zip
3910 Waldemere Ave		Indianapolis	IN	46241
Phone	Title		Number of Employed Hours	
317-794-1312	Senior Quality Manager		520	

Description of Duties

Maintain QMS to ISO standards, prepare quality plans, participate in customer vendor audits, perform root-cause analysis to identify corrective actions, manage medical device supplier relations including supplier qualification/performance evaluation.

Business Name			From - To (MM/YY – MM/YY)	
Exelead - MilliporeSigma (Merck)			11/22-05/23	
Business Address		City	State	Zip
6925 Guion Rd		Indianapolis	IN	46268
Phone	Title		Number of Employed Hours	
317-347-2780	Senior Product Quality Representative		1040	

Description of Duties

Managed QA investigation and client interfaces for product quality issues, CAPA investigations, trained employees on IMF Quality Policy, provide CFR/FDA/ICH guidance, responsible for oversight of deviations, change controls, regulatory compliance.

Business Name			From - To (MM/YY – MM/YY)	
WIT Trade Services			10/21-11/22	
Business Address		City	State	Zip
2301 Reeves Rd		Plainfield	IN	46168
Phone	Title		Number of Employed Hours	
	Quality/Doc Control Manager, ISO Internal Lead Auditor		2240	

Description of Duties

Investigate laboratory equipment events to find root-cause of quality failures with troubleshooting equipment, enable FIFO picking and processing throughout distribution facility, monthly ad hoc metrics/reports, audit readiness.

Business Name			From - To (MM/YY – MM/YY)	
Starkey Hearing Technologies (Closed)			04/21-10/21	
Business Address		City	State	Zip
N/A		Plainfield	IN	46158
Phone	Title		Number of Employed Hours	
888-481-5512	Quality Control Manager		1040	

Description of Duties

Inspection of incoming/outgoing material, completing quality testing, ensuring quality of products maintained throughout Fulfillment process, perform mechanical and electrical testing of incoming medical device components.

Business Name			From - To (MM/YY – MM/YY)	
Johnson & Johnson DHL Logistics 3PL			03/2011 - 04/2021	
Business Address		City	State	Zip
2100 Innovation Blvd (9440 South SR39)		Mooresville	In	46158
Phone	Title		Number of Employed Hours	
317-539-9540	Sr. Quality Manager		20,870	

Description of Duties

Supervised maintaining of all Pharm/Medical device renewal licenses, Managed QA CAPA's Document Control, Risk Assessments, Regulatory Audits and License, Internal Audits, Deviation, Change Control, Medical device and list 1 controlled product

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Rebecca Everett

Original Signature (electronic, copies or stamps not accepted)

25 Aug 2023

Date

I, Rebecca Everett, **certify that as the MDEG Administrator for**

ALOM Technologies Corporation,

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

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

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

Rebecca Everett
Print Name (First, Last)

Rebecca Everett
Original Signature (electronic, copies or stamps not accepted)

25 Aug 2023
Date

Board Use Only	Date Received: 8/31/23

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ALOM Technologies Corporation

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 3910 Waldemere Ave.

City Indianapolis State IN Zip 46241

Mailing Address (if different from physical address) 48021 Warm Springs Blvd

City Fremont State CA Zip 94539

Telephone 510-360-3600 Website https://alom.com/

Licensing Company Email regulatory@alom.com

Section 2: Personal Information

First Rebecca Middle Ann Last Everett

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

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

Mailing Address [redacted]

City Indianapolis State IN Zip 46241

Telephone [redacted] Email reverett@alom.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Indiana University - Purdue University Indianapolis			01/1992 - 01/1993
Address	**City**	**State**	**Zip**
420 University Blvd	Indianapolis	IN	46202
Diploma/Degree obtained, if any			
Associates in Computer IT, Legal Environment Business Environment			

School Name			From - To (MM/YY – MM/YY)
Indiana Business College (Harrison College)			02/1991 - 11/1991
Address	**City**	**State**	**Zip**
550 E Washington St	Indianapolis	IN	46204
Diploma/Degree obtained, if any			
Associates in Communication/Business Management			

School Name			From - To (MM/YY – MM/YY)
Pharmacy Trade School - Walmart/Hawkins			1980-1987
Address	**City**	**State**	**Zip**
1002 W. Taft Road	Sapulpa	Ok	74066
Diploma/Degree obtained, if any			
On the job training by 3 licensed Pharmacist			

School Name			From - To (MM/YY – MM/YY)
Sperry Okla 3rd - 10th grade HS / Arsenal HS 12th grade GED			1983-86
Address	**City**	**State**	**Zip**
1500 E. Michigan St.	Indianapolis	IN	46202
Diploma/Degree obtained, if any			
Yes HS GED			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2020 - current	[redacted]	Plainfield	IN	46168
09/1997 - 04/2020		Monrovia	IN	46157
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
ALOM Technologies Corporation			05/23 - Present	
Business Address		**City**	**State**	**Zip**
3910 Waldemere Ave		Indianapolis	IN	46241
Phone	**Title**		**Number of Employed Hours**	
317-794-1312	Senior Quality Manager		520	
Description of Duties				
Maintain QMS to ISO standards, prepare quality plans, participate in customer vendor audits, perform root-cause analysis to identify corrective actions, manage medical device supplier relations including supplier qualification/performance eval.				

Business Name			From - To (MM/YY – MM/YY)	
Exelead - MilliporeSigma (Merck)			11/22-05/23	
Business Address		**City**	**State**	**Zip**
6925 Guion Rd		Indianapolis	IN	46268
Phone	**Title**		**Number of Employed Hours**	
317-347-27800	Senior Product Quality Representative		1040	
Description of Duties				
Managed QA investigation and client interfaces for product quality issues, CAPA investigations, trained employees on IMF Quality Policy, provide CFR/FDA/ICH guidance, responsible for oversight of deviations, change controls, regulatory compl.				

Business Name			From - To (MM/YY – MM/YY)	
WIT Trade Services			10/21-11/22	
Business Address		**City**	**State**	**Zip**
2301 Reeves Rd		Plainfield	IN	46168
Phone	**Title**		**Number of Employed Hours**	
	Quality/Doc Control Manager, ISO Internal Lead Auditor		2240	
Description of Duties				
Investigate laboratory equipment events to find root-cause of quality failures with troubleshooting equipment, enable FIFO picking and processing throughout distribution facility, monthly ad hoc metrics/reports, audit readiness.				

Business Name			From - To (MM/YY – MM/YY)	
Starkey Hearing Technologies (Closed)			04/21-10/21	
Business Address		**City**	**State**	**Zip**
N/A		Plainfield	IN	46168
Phone	**Title**		**Number of Employed Hours**	
888-481-5512	Quality Control Manager		1040	
Description of Duties				
Inspection of incoming/outgoing material, completing quality testing, ensuring quality of products maintained throughout Fulfillment process, perform mechanical and electrical testing of incoming medical device components.				

Business Name			From - To (MM/YY – MM/YY)	
Johnson & Johnson DHL 3PL			03/11-04/21	
Business Address		**City**	**State**	**Zip**
2100 Innovation Blvd		Mooresville	IN	46158
Phone	**Title**		**Number of Employed Hours**	
317-539-8300	Quality Assurance Manager		20,840	
Description of Duties				
Supervised maintaining of all pharmaceutical/medical device renewal licenses for facility, worked with FDA/DEA/VAWD med device regulations, risk management, protocols, SOPs, validation plans, daily QA training activities.				

Continue on next page if additional space is needed.

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

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

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

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

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

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

28 Aug 2023

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

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

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

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

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

Provide explanation below:

N/A

Rebecca Ewert

Original Signature (electronic, copies or stamps not accepted)

23 Aug 2023

Date

I, Rebecca Everett, **certify that as the designated representative for**

ALOM Technologies Corporation,

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

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

Rebecca Everett

Print Name (First, Last)

Rebecca Everett

Original Signature (electronic, copies or stamps not accepted)

23 Aug 2023

Date

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

Rebecca Everett

Print Name (First, Last)

Rebecca Everett

Original Signature (electronic, copies or stamps not accepted)

25 Aug 2023

Date

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

State of Indiana, ss. County of Hendricks

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

Rebecca Everett

Original Signature

25 Aug 2023

Date

Subscribed and Sworn to before me this 25 day of August 2023

Sheila McGuire

Notary Public Signature

SHEILA MCGUIRE
My Commission Expires
October 23, 2026
Commission Number NP0716462
Owen County

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: ALOM Technologies Corporation

Physical Address: 3910 Waldemere Ave.

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 48021 Warm Springs Blvd.

City: Fremont State: CA Zip: 94539

Telephone: (510) 360-3641 Website: www.alom.com

Licensing Company Email: regulatory@alom.com

Section 2: Personal Information

First: Jakob Middle: _____ Last: Nielsen

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

Date of Bir[redacted] SSN or ITI[redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted]

City: San Jose State: CA Zip: 95126

Telephor[redacted] Email: nielsen@nngroup.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials _____

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

School Name			From - To (MM/YY – MM/YY)	
Technical University of Denmark			01/85-06/88	
Address		City	State	Zip
Anker Engelunds Vej 1		Lyngby	Denmark	2800
Diploma/Degree obtained, if any				
Ph.D.				
School Name			From - To (MM/YY – MM/YY)	
Aarhus University			09/76-06/83	
Address		City	State	Zip
Nordre Ringgade 1		Aarhus	Denmark	8000
Diploma/Degree obtained, if any				
M.S.				
School Name			From - To (MM/YY – MM/YY)	
Risskov Amtsgymnasium			08/73-06/76	
Address		City	State	Zip
Tranekjarvej 70		Risskov	Denmark	8240
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/10 - Present	[redacted]	San Jose	CA	95126
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials

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

Business Name: Nielsen Norman Group				From - To (MM/YY – MM/YY): 08/98-Present
Business Address: 48105 Warm Springs Blvd.		City: Fremont	State: CA	Zip: 94539
Phone: 415-685-4230	Title: Principal			
Description of Duties: Manage the Company				

Business Name: ALOM Technologies Corporation				From - To (MM/YY – MM/YY):
Business Address: 48021 Warm Springs Blvd.		City: Fremont	State: CA	Zip: 94539
Phone:	Title: Director			
Description of Duties: Board Member				

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

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

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

Continue on next page if additional space is needed.

Applicant's initials

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

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

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

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

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

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

Applicant's initials _____

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

Applicant's initials _____

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

This is in response to Question # 4. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/28/2019	N/A	OH	Dayton	Montgomery County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
17-31030		US Bankruptcy Court for the Southern District of Ohio Western Division at Dayton		
Reason/Charge				
Complaint of debtor-in-possession to avoid and recover preference transfers and pursuant to ll U.S.C. Sect. 547 & 550; to				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
GYPC, Inc.		Bankruptcy		
Name of Business/Industry/Entity				
GYPC, Inc.				

Provide explanation below:

Lawsuit: Nielsen Norman Group (NNG) had hired U.S. Motivation to support conferences, including to collect the fees paid by participants. U.S. Motivation discontinued its business. The other creditors sued to have NNG return the collected fees that had been paid to NNG.

Lawsuit was dismissed on August 30, 2022.

Original Signature (electronic, copies or stamps not accepted)

03/29/2023
Date

Applicant's initials

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT DAYTON

IN RE:	:	Case No. 17-31030
		Chapter 11
GYPC, INC.,	:	Judge Guy R. Humphrey
Debtor-In-Possession.	:	

GYPC, INC., PO Box 1805 Dayton, OH 45402 Plaintiff,	:	ADV. PRO. NO. _____
v.	:	
THE NIELSEN NORMAN GROUP c/o Jakob Nielsen, Registered Agent 826 Chapman Street San Jose, CA 95126	:	
Defendant.	:	

COMPLAINT OF DEBTOR-IN-POSSESSION TO AVOID AND RECOVER PREFERENCE TRANSFERS AND PURSUANT TO 11 U.S.C. §§ 547 AND 550; TO DISALLOW ANY AND ALL PROOFS OF CLAIMS FILED OR TO BE FILED BY DEFENDANT; AND FOR COSTS, REASONABLE ATTORNEY FEES AND OTHER RELIEF

NOW COMES GYPC, Inc., successor by merger to US Motivation, Inc., formerly known as General Yellow Pages Consultants, Inc. and formerly doing business as Marquette Group, the Chapter 11 Debtor-In-Possession ("Plaintiff" or "Debtor") herein, by and through counsel, and pursuant to Rule 7001 of the Federal Rules of Bankruptcy Procedure, hereby brings this Complaint against the Defendant listed in the above caption ("Defendant") and states and avers as follows:

BACKGROUND OF THE CONTROVERSY

1. This Court has jurisdiction over this proceeding pursuant to 28 U.S.C. § 1334. This adversary proceeding arises under Title 11 of the United States Code and arises in or is

related to the above-captioned Chapter 11 case now pending before the United States Bankruptcy Court for the Southern District of Ohio, Western Division at Dayton, and has been referred to this Court by the Standing Order of Reference entered in this District on July 30, 1984 pursuant to 28 U.S.C. § 157. This is alleged to be a core proceeding, *inter alia*, pursuant to 28 U.S.C. § 157(b)(2)(A), (E), (F), (H), and (O).

2. Defendant herein is subject to the personal jurisdiction of this Court and venue lies with the Court pursuant to 28 U.S.C. § 1409. Defendant's proper notice address for service is listed in the above caption.

3. Debtor, as Debtor-In-Possession, has standing to bring this proceeding pursuant to 11 U.S.C. §§ 547 and 550. The Debtor's mailing address is listed in the caption.

4. Debtor filed this Chapter 11 Bankruptcy case on March 30, 2017 (the "Petition Date").

5. Within ninety (90) days before the Petition Date, or, to the extent the Defendant is determined to be an "insider," within the one year before the Petition Date (the "Preference Period"), the Debtor transferred funds and/or property to or for the benefit of the Defendant. All transfers made at anytime to or for the benefit of the Defendant within the Preference Period are hereinafter referred to as the "Transfers."

6. The known Transfers are in the amount listed on Exhibit A attached hereto. The total of all Transfers from the Debtor to the Defendant is believed to be in excess of the known Transfers listed on Exhibit "A." Therefore, the Plaintiff alleges the Defendant is also liable for the amount of unknown Transfers in an amount to be determined through discovery in this matter.

7. At the time the Defendant received each of the Transfers, the Debtor was insolvent.

8. At the time the Defendant received each of the Transfers, the Defendant had actual or constructive knowledge of, or is estopped from denying having knowledge of, the Debtor's insolvency.

9. Plaintiff has no adequate remedy at law.

FIRST CLAIM FOR RELIEF – SECTION 547 AVOIDANCE OF PREFERENCE TRANSFERS

10. Plaintiff realleges and incorporates the foregoing paragraphs as if fully rewritten herein.

11. The Plaintiff is entitled to avoid all transfers to the Defendant made during the Preference Period.

12. The Defendant is a pre-petition creditor of the Debtor.

13. Within the Preference Period, the Debtor made the Transfers, which were payments or other transfers of money or other things of value, constituting property in which the Debtor had an interest, to or for the benefit of the Defendant. The Transfers include all transfers of the Debtor's funds or property in which Debtor owned an interest to or for the benefit of the Defendant within the Preference Period.

14. The Transfers were each a "transfer" of an interest of the Debtor in property to or for the benefit of the Defendant within the meaning of 11 U.S.C. § 547(b).

15. The Transfers were made for or on account of antecedent debt(s) owed by the Debtor to the Defendant before the Transfers were made.

16. The Transfers were each made while the Debtor was insolvent.

17. The Transfers have enabled the Defendant to receive: (1) more than the Defendant would receive under Chapter 7 of the Bankruptcy Code; (2) if the Transfers had not been made; and (3) the Defendant received payment of such debts to the extent provided by Chapter 7 of the

Bankruptcy Code.

18. As a direct and proximate result of the foregoing, Plaintiff is entitled to avoid all Transfers and recover same from the Defendant for the benefit of the estate, pursuant to 11 U.S.C. §§ 547 and 550, in the actual amount of the Transfers, to be determined through discovery, but being not less than the total amount set forth on Exhibit "A."

SECOND CLAIM FOR RELIEF – OBJECTION TO ANY AND ALL PROOFS OF CLAIM FILED OR TO BE FILED BY DEFENDANT

19. Plaintiff realleges and incorporates the foregoing paragraphs as if fully rewritten herein.

20. Based on the foregoing, Plaintiff hereby objects, pursuant to 11 U.S.C. § 502 and Rules 3007, 7001, and 9014 of the Federal Rules of Bankruptcy Procedure, to any and all proof of claim filed or to be filed by the Defendant and asks the Court to disallow same. As used herein, the term "Claim" shall include without limitation, both pre and post-petition claims of Defendant, including any claimed administrative expense payable pursuant to 11 U.S.C. § 503.

21. Alternatively, based on the foregoing, Plaintiff hereby requests that the Court disallow any and all claims whatsoever of Defendant unless and until Defendant returns all monies due to Plaintiff, as provided by 11 U.S.C. § 502.

THIRD CLAIM FOR RELIEF – INTEREST, REASONABLE ATTORNEY FEES AND OTHER RELIEF

22. Plaintiff realleges and incorporates the foregoing paragraphs as if fully rewritten herein.

23. Plaintiff is entitled to recover from Defendant prejudgment interest and its costs and expenses incurred in connection with bringing this adversary proceeding, including all reasonable attorneys' fees as well as any other relief, legal or equitable, that this Court determines is appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, based upon the foregoing, demands judgment against the Defendant on its claims for relief as follows:

A. On the First Claim for the Relief, for an Order declaring all Transfers to or for the benefit of the Defendant to be avoidable pursuant to 11 U.S.C. §§ 547 and ordering avoidance and repayment of said monies from the Defendant to the Plaintiff pursuant to 11 U.S.C. §550; and

B. On the Second Claim for Relief, for an Order pursuant to 11 U.S.C. § 502 and Rule 3007 of the Federal Rules of Bankruptcy Procedure disallowing in full any and all claims of Defendant whatsoever, filed or unfiled, until the Defendant has returned to the estate all transfer that are avoidable under 11 U.S.C. §§ 547 and/or 548; and

C. On the Third Claim for Relief, prejudgment interest, attorney's fees and costs, the total amount of which is as yet undetermined.

Respectfully submitted,

COOLIDGE WALL CO., L.P.A.

/s/ Zachary B. White

Patricia J. Friesinger (0072807)
Zachary B. White (0096014)
33 West First Street, Suite 600
Dayton, Ohio 45402
Tel: 937/223-8177 Fax: 937/223-6705
E-Mail: friesinger@coollaw.com
E-Mail: white@coollaw.com
Counsel for Plaintiff/Debtor GYPC, Inc.

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EXHIBIT A

Date	Name	Amount
12/29/2016	913863 Nielsen Norman Group	(9,000.80)
1/6/2017	913863 Nielsen Norman Group	(35,982.26)
1/20/2017	913863 Nielsen Norman Group	(86,556.66)
1/11/2017	Nielsen Norman Group	(1,000.00)
1/17/2017	Nielsen Norman Group	(3,629.00)
1/19/2017	Nielsen Norman Group	(607.00)
1/20/2017	Nielsen Norman Group	(844.00)
1/30/2017	Nielsen Norman Group	(799.00)
2/2/2017	Nielsen Norman Group	(1,457.00)
	Total Sum	**(139,875.72)**

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

Jakob Nielsen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/29/2023

Date

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

State of California, ss. County of Alameda

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

Original Signature

03/29/2023

Date

Subscribed and Sworn to before me this 29 day of MARCH.

Notary Public Signature

LYNETTE MARY LONG
Notary Public - California
Alameda County
Commission # 2431357
My Comm. Expires Jan 14, 2027

(Seal)

Applicant's initials JN

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

This is in response to Question # 4. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/26/2005	05/14/2007	CA	Fremont	Alameda County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
RG 05215092	Superior Court of the State of California, County of Alameda

Reason/Charge
Breach of contract and reimbursement of monetary value

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

Name of Business/Industry/Entity
Lexar Media, Inc.

Provide explanation below:

Background: ALOM customer consigned hardware for assembly and fulfillment services. ALOM's truck was subjected to a transit theft. Lexar Media demanded monetary value for damages and stolen goods.

The case was resolved by ALOM's insurance company, ALOM and the customer settled out of court on March 21, 2006.

Original Signature (electronic, copies or stamps not accepted)

3/29/2023
Date

Applicant's initials HK

ENDORSED
FILED
ALAMEDA COUNTY
MAY 14 2007
CLERK OF THE SUPERIOR COURT
BY DOROTHY DUCKETT, DEPUTY

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name and Address):	TELEPHONE NO:	FOR COURT USE ONLY
Adam C. Brown (SBN 161951)/Janet K. Haines (SBN 242374) Brown & Associates, PLC 11140 Fair Oaks Blvd., Suite 100 Fair Oaks, California 95628	(916) 859-4910 FAX NO.: (916) 859-4911	
ATTORNEY FOR (Name): LEXAR MEDIA, INC., Plaintiff		
Insert name of court and name of judicial district and branch court, if any: SUPERIOR COURT OF CALIFORNIA, ALAMEDA COUNTY		
PLAINTIFF/PETITIONER: LEXAR MEDIA, INC. DEFENDANT/RESPONDENT: ALOM TECHNOLOGIES CORPORATION		

REQUEST FOR DISMISSAL

- [ ] Personal Injury, Property Damage, or Wrongful Death
  - [ ] Motor Vehicle
  - [ ] Other
- [ ] Family Law
- [ ] Eminent Domain
- [X] Other (specify): Theft of cargo

CASE NUMBER: RG05215092

- A conformed copy will not be returned by the clerk unless a method of return is provided with the document. -

1. **TO THE CLERK:** Please dismiss this action as follows:
   a. (1) [X] With prejudice (2) [ ] Without prejudice

   b. (1) [X] Complaint (2) [ ] Petition
   (3) [ ] Cross-complaint filed by *(name)*: on *(date)*:
   (4) [ ] Cross-complaint filed by *(name)*: on *(date)*:
   (5) [X] Entire action of all parties and all causes of action
   (6) [X] Other *(specify)*:*
   Each side to bear their own attorneys' fees and costs

Date: May 7, 2007

Janet K. Haines
(TYPE OR PRINT NAME OF [X] ATTORNEY [ ] PARTY WITHOUT ATTORNEY)

Janet K. Haines
(SIGNATURE)

Attorney or party without attorney for:
[X] Plaintiff/Petitioner [ ] Defendant/Respondent
[ ] Cross-complainant

* If dismissal requested is of specified parties only, of specified causes of action only, or of specified cross-complaints only, so state and identify the parties, causes of action, or cross-complaints to be dismissed.

2. **TO THE CLERK:** Consent to the above dismissal is hereby given.**

Date:

(TYPE OR PRINT NAME OF [ ] ATTORNEY [ ] PARTY WITHOUT ATTORNEY)

(SIGNATURE)

Attorney or party without attorney for:
[ ] Plaintiff/Petitioner [ ] Defendant/Respondent
[ ] Cross-complainant

** If a cross-complaint or Response (Family Law) seeking affirmative relief is on file, the attorney for cross-complainant (respondent) must sign this consent if required by Code of Civil Procedure section 581 (i) or (j).

(To be completed by clerk) MAY 14 2007

3. [X] Dismissal entered as requested on *(date)*:
4. [ ] Dismissal entered on *(date)*: as to only *(name)*:
5. [ ] Dismissal not entered as requested for the following reasons *(specify)*:

6. [ ] a. Attorney or party without attorney notified on *(date)*:
   b. Attorney or party without attorney not notified. Filing party failed to provide
   [ ] a copy to conform [ ] means to return conformed copy

Date: MAY 14 2007 PAT S. SWEETEN Clerk, by DOROTHY DUCKETT, Deputy

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

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/25/2007	07/21/2009	CA	Fremont	Alameda County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
RG 07328171		Superior Court of the State of California, County of Alameda		
Reason/Charge				
Employment, wage and hour				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Sandra Rivera, Cesar Robles & Vicky Penaloza		Lawsuit		
Name of Business/Industry/Entity				
Lexar Media, Inc.				

Provide explanation below:

Three temporary agency employees, assigned to work at ALOM Technologies Corporation, submitted a claim against their employer, United Temp Services, Inc. and ALOM Technologies Corporation.

July 21, 2009 Notice of acceptance of 998 offer to compromise by defendant ALOM Technologies Corporation to plaintiffs.

Original Signature (electronic, copies or stamps not accepted)

3/29/2023
Date

Applicant's initials HK

PROOF OF SERVICE

I, Karla Donis, declare as follows:

I am over the age of eighteen years and not a party to the within entitled action. I am employed with the law offices of Talamantes/Villegas/Carrera, LLP, located at 170 Columbus Ave.,Ste. 300, San Francisco, CA 94133.

On July 21, 2009, I served the attached:

1. **NOTICE OF ACCEPTANCE OF 998 OFFER TO COMPROMISE BY DEFENDANT ALOM TECHNOLOGIES CORPORATION TO PLAINTIFF ANASTACIO RIVERA;**

2. **NOTICE OF ACCEPTANCE OF 998 OFFER TO COMPROMISE BY DEFENDANT ALOM TECHNOLOGIES CORPORATION TO PLAINTIFF VICKY PEÑALOZA;**

3. **NOTICE OF ACCEPTANCE OF 998 OFFER TO COMPROMISE BY DEFENDANT ALOM TECHNOLOGIES CORPORATION TO PLAINTIFF CESAR ROBLES.**

on the interested parties in said action, by placing a true copy thereof in sealed envelope(s) addressed as follows:

Timothy C. Davis
The Davis Law Firm
625 Market St., 12th Floor
San Francisco, CA 94105-3302

Attorneys for Defendant Alom Technologies, Inc.

and served the named document(s) in the manner indicated below:

☐ **BY U.S. MAIL**: I placed true and correct copies of the above documents sealed in envelope(s) and addressed to the addressee(s) at San Francisco, CA for collection and mailing with the United States Postal Service, and in the ordinary course of business, correspondence placed for collection on a particular day is deposited with the United States Postal Service that same day.

☒ **BY PERSONAL SERVICE**: I placed and sealed in envelope(s) addressed to the addressee(s) true and correct copies of the above documents and I caused such envelope(s) to be delivered by hand on the office(s) of the addressee(s).

☐ **BY FACSIMILE**: I caused true and correct copies of the above documents to be transmitted to the facsimile numbers of each office listed in this service document. I caused the transmitting facsimile machine to print a record of the transmission. The transmission was reported as complete and without error.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on July 21, 2009, at San Francisco, California.

Karla Donis

(1) 5

VIRGINIA R. VILLEGAS, State Bar #179062
JENNIFER A. REISCH, State Bar #223671
TALAMANTES/VILLEGAS/CARRERA, LLP
170 Columbus Ave., Ste. 300
San Francisco, CA 94133
Telephone: (415) 989-8000
Facsimile: (415) 989-8028

Attorneys for Plaintiffs SANDRA RIVERA, a.k.a. ANASTACIO RIVERA, MONICA ROBLES, a.k.a. CESAR ROBLES, and VICKY PEÑALOZA

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ALAMEDA

(UNLIMITED JURISDICTION)

SANDRA RIVERA a.k.a. ANASTACIO RIVERA, MONICA ROBLES a.k.a. CESAR ROBLES, and VICKY PENALOZA, Plaintiffs, vs. ALOM TECHNOLOGIES, INC., a Corporation: UNITED TEMP SERVICES, INC., a Corporation; IVONNE GARCIA, an individual; and DOES 1 through 20, Inclusive, Defendants.	Case No.: RG 07328171 **PROOF OF SERVICE**

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

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/18/2013	09/20/2013	CA	Oakland	Alameda County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
RG 13684036		Superior Court of the State of California, County of Alameda		
Reason/Charge				
Breach of contract, specific performance & declaratory relief				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
T&G 2009, LLC		Lawsuit		
Name of Business/Industry/Entity				
T&G 2009, LLC				

Provide explanation below:

Background: ALOM had a supplier, Global Publishing owned by several people and entities. The business was discontinued, and the owners had a falling out. The lawsuit demanded that ALOM pay one particular entity.

Court granted ALOM's interpleader on September 20, 2013 and the lawsuit was dismissed.

Original Signature (electronic, copies or stamps not accepted)

3/29/2023
Date

Applicant's initials HK

SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):

ALOM TECHNOLOGIES CORPORATION, DANA VIDEO MEDIA, INC., Additional Parties Attachment form is attached.

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):

T&G 2009, LLC, a California limited liability company

ENDORSED
FILED
ALAMEDA COUNTY

JUN 18 2013

CLERK OF THE SUPERIOR COURT
By CHERYL CLARK
Deputy

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site (*www.lawhelpcalifornia.org*), the California Courts Online Self-Help Center (*www.courtinfo.ca.gov/selfhelp*), or by contacting your local court or county bar association. NOTE: The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.

¡AVISO! Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

CASE NUMBER (Número del Caso): RG13684036

The name and address of the court is:
(*El nombre y dirección de la corte es*): ALAMEDA COUNTY SUPERIOR
1225 FALLON STREET
OAKLAND, CA 94612

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(*El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es*):
PAUL G. MINOLETTI, ESQ., 1 WATERS PARK DR, STE 210, SAN MATEO, CA 94403 650-638-9600

Leah T. Wilson

DATE (Fecha): JUN 18 2013 Executive Officer/Clerk of the Superior Court (Secretario) CHERYL CLARK (Deputy (Adjunto))

(For proof of service of this summons, use Proof of Service of Summons (form POS-010).)
(Para prueba de entrega de este citatión use el formulario Proof of Service of Summons, (POS-010)).

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of (*specify*):
3. ☒ on behalf of (*specify*): ALOM Technologies Corporation
   under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other (*specify*):
4. ☐ by personal delivery on (*date*):

Page 1 of 1

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]

SUMMONS

Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

SUM-200(A)

SHORT TITLE:	CASE NUMBER:
T&G 2009, LLC v. ALOM TECHNOLOGIES, et al.	RG 13684036

INSTRUCTIONS FOR USE

- This form may be used as an attachment to any summons if space does not permit the listing of all parties on the summons.
- If this attachment is used, insert the following statement in the plaintiff or defendant box on the summons: "Additional Parties Attachment form is attached."

List additional parties *(Check only one box. Use a separate page for each type of party.):*

☐ Plaintiff ☑ Defendant ☐ Cross-Complainant ☐ Cross-Defendant

MEDIA BLASTER, INC., INNERWORKING, INC., and DOES 1 to 30, inclusive,

Form Adopted for Mandatory Use
Judicial Council of California
SUM-200(A) [Rev. January 1, 2007]

ADDITIONAL PARTIES ATTACHMENT
Attachment to Summons

CM-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
PAUL G. MINOLETTI, ESQ. SBN: 118192
LAW OFFICES OF PAUL G. MINOLETTI
1 WATERS PARK DRIVE, SUITE 210
SAN MATEO, CA 94403
TELEPHONE NO.: 650-638-9600 FAX NO.:
ATTORNEY FOR (Name): plaintiff T&G 209, LLC

FOR COURT USE ONLY

ENDORSED
FILED
ALAMEDA COUNTY

JUN 18 2013

CLERK OF THE SUPERIOR COURT
BY CHERYL CLARK
Deputy

SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA
STREET ADDRESS: 1225 FALLON STREET
MAILING ADDRESS:
CITY AND ZIP CODE: OAKLAND, CA 94612
BRANCH NAME:

CASE NAME:
T&G 2009, LLC v. ALOM TECHNOLOGIES, et al.

CASE NUMBER: RG 13684036

JUDGE:
DEPT:

CIVIL CASE COVER SHEET

☑ Unlimited (Amount demanded exceeds $25,000) ☐ Limited (Amount demanded is $25,000 or less)

Complex Case Designation

☐ Counter ☐ Joinder

Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

Items 1–6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort
- ☐ Auto (22)
- ☐ Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- ☐ Asbestos (04)
- ☐ Product liability (24)
- ☐ Medical malpractice (45)
- ☐ Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
- ☐ Business tort/unfair business practice (07)
- ☐ Civil rights (08)
- ☐ Defamation (13)
- ☐ Fraud (16)
- ☐ Intellectual property (19)
- ☐ Professional negligence (25)
- ☐ Other non-PI/PD/WD tort (35)

Employment
- ☐ Wrongful termination (36)
- ☐ Other employment (15)

Contract
- ☑ Breach of contract/warranty (06)
- ☐ Rule 3.740 collections (09)
- ☐ Other collections (09)
- ☐ Insurance coverage (18)
- ☐ Other contract (37)

Real Property
- ☐ Eminent domain/inverse condemnation (14)
- ☐ Wrongful eviction (33)
- ☐ Other real property (26)

Unlawful Detainer
- ☐ Commercial (31)
- ☐ Residential (32)
- ☐ Drugs (38)

Judicial Review
- ☐ Asset forfeiture (05)
- ☐ Petition re: arbitration award (11)
- ☐ Writ of mandate (02)
- ☐ Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403)
- ☐ Antitrust/Trade regulation (03)
- ☐ Construction defect (10)
- ☐ Mass tort (40)
- ☐ Securities litigation (28)
- ☐ Environmental/Toxic tort (30)
- ☐ Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
- ☐ Enforcement of judgment (20)

Miscellaneous Civil Complaint
- ☐ RICO (27)
- ☐ Other complaint (*not specified above*) (42)

Miscellaneous Civil Petition
- ☐ Partnership and corporate governance (21)
- ☐ Other petition (*not specified above*) (43)

2. This case ☐ is ☑ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:

BY FAX

a. ☐ Large number of separately represented parties
b. ☐ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
c. ☐ Substantial amount of documentary evidence
d. ☐ Large number of witnesses
e. ☐ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
f. ☐ Substantial postjudgment judicial supervision

3. Remedies sought (*check all that apply*): a. ☑ monetary b. ☑ nonmonetary; declaratory or injunctive relief c. ☐ punitive
4. Number of causes of action (*specify*): 1
5. This case ☐ is ☑ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. (*You may use form CM-015.*)

Date: JUNE 17, 2013
PAUL G. MINOLETTI, ESQ.
(TYPE OR PRINT NAME)

▶ Paul G. Minoletti
(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

Form Adopted for Mandatory Use
Judicial Council of California
CM-010 [Rev. July 1, 2007]

CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 2.30, 3.220, 3.400–3.403, 3.740;
Cal. Standards of Judicial Administration, std. 3.10
www.courtinfo.ca.gov

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you must complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the primary cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)–Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice–Physicians & Surgeons
  - Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach–Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case–Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ–Administrative Mandamus
  - Writ–Mandamus on Limited Court Case Matter
  - Writ–Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal–Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief From Late Claim
  - Other Civil Petition

ENDORSED
FILED
ALAMEDA COUNTY

JUN 18 2013

CLERK OF THE SUPERIOR COURT
By CHERYL CLARK
Deputy

PAUL G. MINOLETTI, ESQ./SBN: 118192
LAW OFFICES OF PAUL G. MINOLETTI
1 Waters Park Drive, Suite 210
San Mateo, CA 94403
Tel: 650-638-9600
Fax: 650-638-9604

Attorneys for Plaintiff
T&G 2009, LLC

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

UNLIMITED JURISDICTION

T&G 2009, LLC, a California limited liability company,

Plaintiff,

vs.

ALOM TECHNOLOGIES CORPORATION, DANA VIDEO MEDIA, INC., MEDIA BLASTER, INC., INNERWORKING, INC.,and DOES 1 to 30, inclusive,

Defendants.

Case No. RG 13684036

COMPLAINT FOR DAMAGES:

1) BREACH OF CONTRACT
2) SPECIFIC PERFORMANCE
3) DECLARATORY RELIEF

BY FAX

Plaintiff complains and for causes of action alleges as follows:

PRELIMINARY ALLEGATIONS

1. Plaintiff T&G 2009, LLC, is, and at all times herein mentioned was, a limited liability company organized and existing under the laws of the State of California with principal offices

located at 1208 E. Arques Avenue, Suite 108 in the City of Sunnyvale, County of Santa Clara, State of California.

2. Defendant ALOM TECHNOLOGIES CORPORATION, is, and at all times herein mentioned, was a Corporation organized and existing under the laws of the State of California with principal offices located at 48105 Warm Springs Blvd., in the City of Fremont, County of Alameda.

3. Defendant DANA VIDEO MEDIA, INC., is, based on information and belief, a business organization, form unknown, with last known business address located at 178 Rue Merizzi, in the City of Ville Saint-Laurent, Provence of Quebec, Canada.

4. Defendant MEDIA BLASTER, INC., based on information and belief, is, and at all times herein mentioned, was a Corporation organized and existing under the laws of the State of New York with principal offices located at 1001 Avenue of the Stars, Suite 420, in the City of New York, State of New York.

5. Defendant INNERWORKING, INC., based on information and belief, is, and at all times herein mentioned, was a Corporation organized and existing under the laws of the State of Delaware with principal offices located at 600 W. Chicago Avenue, Suite 850, in the City of Chicago, State of Illinois.

6. Plaintiff is ignorant of the true names and capacities of defendants sued herein as DOES 1 to 30, inclusive, and therefore sues these defendants by such fictitious names. Plaintiff will

amend this complaint to allege their true names and capacities when ascertained.

7. Jurisdiction and venue is proper in this court because each named defendant entered into a contract for goods with plaintiff's assignor, either Global Publishing, Inc. or GP Distribution, in which each named defendant agreed to submit to the jurisdiction and venue of the courts within the County of Alameda, State of California.

FIRST CAUSE OF ACTION
(Breach of Contract)

8. Plaintiff repeats, re-alleges, and incorporates by reference, all other paragraphs.

9. Defendants, ALOM TECHNOLOGIES CORPORATION, DANA VIDEO MEDIA, INC., MEDIA BLASTER, INC., INNERWORKING, INC. and DOES 1 to 30, inclusive, each entered into an agreement beginning in September of 2012 with plaintiff's predecessors in interest, Global Publishing, Inc. and/or GP Distribution, whereby defendants purchased products which were manufactured and shipped to defendants, and each of them, in September and October of 2012, but defendants, and each of them, did not pay the amounts due and owing to plaintiff's predecessor in interest, Global Publishing, Inc. for such orders and shipped product.

10. The plaintiff and/or plaintiff's predecessors in interest, Global Publishing, Inc. and/or GP Distribution, performed all of

their obligations under the terms of the agreements with defendants, including shipping the requested products to defendants, and providing defendants with invoices.

11. Plaintiff obtained from Global Publishing, Inc. and/or GP Distribution, a Promissory Note dated May 18, 2012, which Note pledged as security all of the existing and future account receivables from defendants to plaintiff upon default. Global Publishing, Inc. and/or GP Distribution defaulted on the Note on August 30, 2012, which entitles plaintiff to collect the accounts receivable from defendants. Plaintiff perfected its security interest in the accounts receivable by two (2) UCC-1 Financing Statement filings with the California Secretary of State on May 20, 2012.

12. Plaintiff has demanded that defendants, and each of them, pay to plaintiff all of the amounts owed to Global Publishing, Inc. and/or GP Distribution, but defendants, and each of them, have refused to pay plaintiff.

13. As of October 31, 2012, defendant ALOM TECHNOLOGIES CORPORATION owes plaintiff the sum of $41,140.52, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $41,140.52, plus interest at the rate of one percent (1%) per month until paid.

14. As of October 31, 2012, defendant DANA VIDEO MEDIA, INC. owes plaintiff the sum of $81,335.85, which sum has not been paid,

in part or in full, and there is now due and owing to the plaintiff the sum of $81,335.85, plus interest at the rate of one percent (1%) per month until paid.

15. As of October 31, 2012, defendant MEDIA BLASTER, INC. owes plaintiff the sum of $102,916.00, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $102,916.00, plus interest at the rate of one percent (1%) per month until paid.

16. As of October 31, 2012, defendant INNERWORKING, INC. owes plaintiff the sum of $45,089.00, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $45,089.00, plus interest at the rate of one percent (1%) per month until paid.

17. Plaintiff is also entitled to costs and attorney's fees pursuant to the agreement.

SECOND CAUSE OF ACTION
(Specific Performance)

18. Plaintiff repeats, re-alleges, and incorporates by reference, all other paragraphs.

19. On or about May 18, 2012, for valuable consideration, Global Publishing, Inc. executed a written Promissory Note in favor of plaintiff for a line of credit/loan up to the principal sum of One Million Dollars ($1,000,000.00), bearing interest at the rate of six percent (6%) per annum and requiring timely payments. To

secure payment of the principal and interest as provided in the Promissory Note, the note is collateralized by all of the trade accounts receivable, including but not limited to all receivables of Global Publishing, Inc. and its subsidiary, GP Distribution Group.

20. Global Publishing, Inc. defaulted on the Note on August 30, 2012, which entitles plaintiff to collect the accounts receivable from defendants. Plaintiff perfected its security interest in the accounts receivable by two (2) UCC-1 Financing Statement filings with the California Secretary of State on May 20, 2012.

21. Plaintiff has demanded that defendants, and each of them, pay to plaintiff all of the amounts owed to either Global Publishing, Inc. and/or GP Distribution, a subsidiary of Global Publishing, Inc., but defendants, and each of them, have refused to pay plaintiff.

22. As of October 31, 2012, defendant ALOM TECHNOLOGIES CORPORATION owes plaintiff the sum of $41,140.52, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $41,140.52, plus interest at the rate of one percent (1%) per month until paid.

23. As of October 31, 2012, defendant DANA VIDEO MEDIA, INC. owes plaintiff the sum of $81,335.85, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff

the sum of $81,335.85, plus interest at the rate of one percent (1%) per month until paid.

24. As of October 31, 2012, defendant MEDIA BLASTER, INC. owes plaintiff the sum of $102,916.00, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $102,916.00, plus interest at the rate of one percent (1%) per month until paid.

25. As of October 31, 2012, defendant INNERWORKING, INC. owes plaintiff the sum of $45,089.00, which sum has not been paid, in part or in full, and there is now due and owing to the plaintiff the sum of $45,089.00, plus interest at the rate of one percent (1%) per month until paid.

26. Plaintiff is also entitled to costs and attorney's fees pursuant to the agreement.

27. Plaintiff has no adequate remedy at law to enforce the foregoing security interest pursuant to the secured loans.

THIRD CAUSE OF ACTION
(Declaratory Relief)

28. Plaintiff repeats, re-alleges, and incorporates by reference, all other paragraphs.

29. An actual controversy has arisen and now exists between plaintiff and defendants concerning their respective rights and duties in that plaintiff contends that defendants must pay to plaintiff all amounts owed by defendants to Global Publishing, Inc.

and/or its subsidiary GP Distribution Group, whereas defendants dispute these contentions and contend that they are not required to pay plaintiff said amounts owed.

30. Plaintiff desires a judicial determination of its rights and obligations, and a declaration that plaintiff is entitled to the full sums owed by defendants to Global Publishing, Inc. and its subsidiary GP Distribution Group as set forth herein.

31. A judicial declaration is necessary and appropriate at this time under the circumstances in order that plaintiff may ascertain its rights and obligations and to prevent such further losses of capital and interest on the monies owed, and the costs and fees incurred to collect said monies owed, and to settle all claims as between the parties hereto.

WHEREFORE, plaintiff prays for judgment against the defendants, and each of them, as follows:

1. For a judicial determination that plaintiff is entitled to all of the monies owed by the defendants, and each of them, to Global Publishing, Inc. and/or its subsidiary GP Distribution Group pursuant to the secured loans and California Commercial Code §9-406 and 9-607, and that such amounts owed are to be paid directly to plaintiff;

2. For judgment in favor of plaintiff in the principal sum of $41,140.52 against defendant ALOM TECHNOLOGIES CORPORATION;

3. For judgment in favor of plaintiff in the principal sum of $81,335.85 against defendant DANA VIDEO MEDIA, INC.;

4. For judgment in favor of plaintiff in the principal sum of $102,916.00 against defendant MEDIA BLASTER, INC.;

5. For judgment in favor of plaintiff in the principal sum of $45,089.00 against defendant INNERWORKING, INC.;

6. For the appointment of a receiver to collect any and all accounts payable by defendants for product supplied to defendants by Global Publishing, Inc. and/or its subsidiary GP Distribution Group in connection with the invoices submitted to defendants for the product delivered;

7. For interest on the monies owed;

8. For reasonable attorney's fees;

9. For costs of suit incurred herein; and

10. For such other and further relief as the court deems just and proper.

Dated: June 17, 2013

Paul G. Minoletti

PAUL G. MINOLETTI, ESQ.
Attorney for Plaintiff
T&G 2009, LLC

Superior Court of California, County of Alameda
Alternative Dispute Resolution (ADR) Information Packet

The person who files a civil lawsuit (plaintiff) must include the ADR Information Packet with the complaint when serving the defendant. Cross complainants must serve the ADR Information Packet on any new parties named to the action.

The Court *strongly encourages* the parties to use some form of ADR before proceeding to trial. You may choose ADR by:

- Indicating your preference on Case Management Form CM-110;
- Filing the Stipulation to ADR and Delay Initial Case Management Conference for 90 Days (a local form included with the information packet); or
- Agree to ADR at your Initial Case Management Conference.

QUESTIONS? Call (510) 891-6055. Email adrprogram@alameda.courts.ca.gov
Or visit the court's website at http://www.alameda.courts.ca.gov/adr

What Are The Advantages Of Using ADR?

- ***Faster*** – Litigation can take years to complete but ADR usually takes weeks or months.
- ***Cheaper*** – Parties can save on attorneys' fees and litigation costs.
- ***More control and flexibility*** – Parties choose the ADR process appropriate for their case.
- ***Cooperative and less stressful*** – In mediation, parties cooperate to find a mutually agreeable resolution.
- ***Preserve Relationships*** – A mediator can help you effectively communicate your interests and point of view to the other side. This is an important benefit when you want to preserve a relationship.

What Is The Disadvantage Of Using ADR?

- ***You may go to court anyway*** – If you cannot resolve your dispute using ADR, you may still have to spend time and money resolving your lawsuit through the courts.

What ADR Options Are Available?

- ***Mediation*** – A neutral person (mediator) helps the parties communicate, clarify facts, identify legal issues, explore settlement options, and agree on a solution that is acceptable to all sides.
  - **Court Mediation Program**: Mediators do not charge fees for the first two hours of mediation. If parties need more time, they must pay the mediator's regular fees.

Some mediators ask for a deposit before mediation starts which is subject to a refund for unused time.

- **Private Mediation:** This is mediation where the parties pay the mediator's regular fees and may choose a mediator outside the court's panel.

- ***Arbitration*** – A neutral person (arbitrator) hears arguments and evidence from each side and then decides the outcome of the dispute. Arbitration is less formal than a trial and the rules of evidence are often relaxed. Arbitration is effective when the parties want someone other than themselves to decide the outcome.

  - **Judicial Arbitration Program** (non-binding): The judge can refer a case or the parties can agree to use judicial arbitration. The parties select an arbitrator from a list provided by the court. If the parties cannot agree on an arbitrator, one will be assigned by the court. There is no fee for the arbitrator. The arbitrator must send the decision (award of the arbitrator) to the court. The parties have the right to reject the award and proceed to trial.

  - **Private Arbitration** (binding and non-binding) occurs when parties involved in a dispute either agree or are contractually obligated. This option takes place outside of the courts and is normally binding meaning the arbitrator's decision is final.

Mediation Service Programs In Alameda County

Low cost mediation services are available through non-profit community organizations. Trained volunteer mediators provide these services. Contact the following organizations for more information:

SEEDS Community Resolution Center
1968 San Pablo Avenue, Berkeley, CA 94702-1612
Telephone: (510) 548-2377 Website: www.seedsccr.org
Their mission is to provide mediation, facilitation, training and education programs in our diverse communities – Services that Encourage Effective Dialogue and Solution-making.

Center for Community Dispute Settlement
291 McLeod Street, Livermore, CA 94550
Telephone: (925) 373-1035 Website: www.trivalleymediation.com
CCDS provides services in the Tri-Valley area for all of Alameda County.

For Victim/Offender Restorative Justice Services
Catholic Charities of the East Bay: Oakland
433 Jefferson Street, Oakland, CA 94607
Telephone: (510) 768-3100 Website: www.coeb.org
Mediation sessions involve the youth, victim, and family members work toward a mutually agreeable restitution agreement.

ALA ADR-001

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):	FOR COURT USE ONLY
TELEPHONE NO.: FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR (Name):	
SUPERIOR COURT OF CALIFORNIA, ALAMEDA COUNTY STREET ADDRESS: MAILING ADDRESS: CITY AND ZIP CODE: BRANCH NAME:	
PLAINTIFF/PETITIONER: DEFENDANT/RESPONDENT:	
STIPULATION TO ATTEND ALTERNATIVE DISPUTE RESOLUTION (ADR) AND DELAY INITIAL CASE MANAGEMENT CONFERENCE FOR 90 DAYS	CASE NUMBER:

INSTRUCTIONS: All applicable boxes must be checked, and the specified information must be provided.

This stipulation is effective when:

- All parties have signed and filed this stipulation with the Case Management Conference Statement at least 15 days before the initial case management conference.
- A copy of this stipulation has been received by the ADR Program Administrator, 1225 Fallon Street, Oakland, CA 94612.

1. Date complaint filed: _____. An **Initial Case Management Conference** is scheduled for:

   Date: Time: Department:

2. Counsel and all parties certify they have met and conferred and have selected the following ADR process (*check one*):

   ☐ Court mediation ☐ Judicial arbitration
   ☐ Private mediation ☐ Private arbitration

3. All parties agree to complete ADR within 90 days and certify that:

   a. No party to the case has requested a complex civil litigation determination hearing;
   b. All parties have been served and intend to submit to the jurisdiction of the court;
   c. All parties have agreed to a specific plan for sufficient discovery to make the ADR process meaningful;
   d. Copies of this stipulation and self-addressed stamped envelopes are provided for returning endorsed filed stamped copies to counsel and all parties;
   e. Case management statements are submitted with this stipulation;
   f. All parties will attend ADR conferences; and,
   g. The court will not allow more than 90 days to complete ADR.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date:

_____ ▶ _____
(TYPE OR PRINT NAME) (SIGNATURE OF PLAINTIFF)

Date:

_____ ▶ _____
(TYPE OR PRINT NAME) (SIGNATURE OF ATTORNEY FOR PLAINTIFF)

Form Approved for Mandatory Use
Superior Court of California,
County of Alameda
ALA ADR-001 [New January 1, 2010]

Cal. Rules of Court, rule 3.221(a)(4)

ALA ADR-001

PLAINTIFF/PETITIONER: DEFENDANT/RESPONDENT:	CASE NUMBER:

Date:

_____ ▶ _____

(TYPE OR PRINT NAME) (SIGNATURE OF DEFENDANT)

Date:

_____ ▶ _____

(TYPE OR PRINT NAME) (SIGNATURE OF ATTORNEY FOR DEFENDANT)

Form Approved for Mandatory Use
Superior Court of California
County of Alameda
ALA ADR-001 [New January 1, 2010]

STIPULATION TO ATTEND ALTERNATIVE DISPUTE RESOLUTION (ADR) AND DELAY INITIAL CASE MANAGEMENT CONFERENCE FOR 90 DAYS

Cal. Rules of Court, rule 3.221(c)(4)

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

This is in response to Question # 4. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/02/2021	N/A	CA	Oakland	Alameda County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
RG 21107257		Superior Court of California, County of Alameda		
Reason/Charge				
Wrongful termination of employment				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Deblin Mateo Gonzalez Ordonez			Lawsuit	
Name of Business/Industry/Entity				
Individual				

Provide explanation below:

A temporary agency employee, who was assigned for a period to work at ALOM Technologies Corporation, submitted a claim against his employer, Silicon Valley Technical Staffing, and ALOM Technologies Corporation, as summarized in the attached Summons dated August 2, 2021.

The lawsuit was settled in mediation on May 17, 2022.

Original Signature (electronic, copies or stamps not accepted)

3/29/2023
Date

Applicant's initials HK

SUM-100

SUMMONS
(CITACION JUDICIAL)

NOTICE TO DEFENDANT:
(AVISO AL DEMANDADO):
SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC; ALOM TECHNOLOGIES CORPORATION, a California Corporation; and DOES 1-30, inclusive,

YOU ARE BEING SUED BY PLAINTIFF:
(LO ESTÁ DEMANDANDO EL DEMANDANTE):
DEBLIN MATEO GONZALEZ ORDONEZ, an individual;

FOR COURT USE ONLY
(SOLO PARA USO DE LA CORTE)

E-FILED
AUG - 2 2021
K. Ghee

NOTICE! You have been sued. The court may decide against you without your being heard unless you respond within 30 days. Read the information below.

You have 30 CALENDAR DAYS after this summons and legal papers are served on you to file a written response at this court and have a copy served on the plaintiff. A letter or phone call will not protect you. Your written response must be in proper legal form if you want the court to hear your case. There may be a court form that you can use for your response. You can find these court forms and more information at the California Courts Online Self-Help Center *(www.courtinfo.ca.gov/selfhelp)*, your county law library, or the courthouse nearest you. If you cannot pay the filing fee, ask the court clerk for a fee waiver form. If you do not file your response on time, you may lose the case by default, and your wages, money, and property may be taken without further warning from the court.

There are other legal requirements. You may want to call an attorney right away. If you do not know an attorney, you may want to call an attorney referral service. If you cannot afford an attorney, you may be eligible for free legal services from a nonprofit legal services program. You can locate these nonprofit groups at the California Legal Services Web site *(www.lawhelpcalifornia.org)*, the California Courts Online Self-Help Center *(www.courtinfo.ca.gov/selfhelp)*, or by contacting your local court or county bar association. **NOTE:** The court has a statutory lien for waived fees and costs on any settlement or arbitration award of $10,000 or more in a civil case. The court's lien must be paid before the court will dismiss the case.

¡AVISO! *Lo han demandado. Si no responde dentro de 30 días, la corte puede decidir en su contra sin escuchar su versión. Lea la información a continuación.*

Tiene 30 DÍAS DE CALENDARIO después de que le entreguen esta citación y papeles legales para presentar una respuesta por escrito en esta corte y hacer que se entregue una copia al demandante. Una carta o una llamada telefónica no lo protegen. Su respuesta por escrito tiene que estar en formato legal correcto si desea que procesen su caso en la corte. Es posible que haya un formulario que usted pueda usar para su respuesta. Puede encontrar estos formularios de la corte y más información en el Centro de Ayuda de las Cortes de California (www.sucorte.ca.gov), en la biblioteca de leyes de su condado o en la corte que le quede más cerca. Si no puede pagar la cuota de presentación, pida al secretario de la corte que le dé un formulario de exención de pago de cuotas. Si no presenta su respuesta a tiempo, puede perder el caso por incumplimiento y la corte le podrá quitar su sueldo, dinero y bienes sin más advertencia.

Hay otros requisitos legales. Es recomendable que llame a un abogado inmediatamente. Si no conoce a un abogado, puede llamar a un servicio de remisión a abogados. Si no puede pagar a un abogado, es posible que cumpla con los requisitos para obtener servicios legales gratuitos de un programa de servicios legales sin fines de lucro. Puede encontrar estos grupos sin fines de lucro en el sitio web de California Legal Services, (www.lawhelpcalifornia.org), en el Centro de Ayuda de las Cortes de California, (www.sucorte.ca.gov) o poniéndose en contacto con la corte o el colegio de abogados locales. AVISO: Por ley, la corte tiene derecho a reclamar las cuotas y los costos exentos por imponer un gravamen sobre cualquier recuperación de $10,000 ó más de valor recibida mediante un acuerdo o una concesión de arbitraje en un caso de derecho civil. Tiene que pagar el gravamen de la corte antes de que la corte pueda desechar el caso.

CASE NUMBER (Número del Caso): 21107257 RG

The name and address of the court is:
(El nombre y dirección de la corte es):
Superior Court of California County of Alameda
1225 Fallon Street
Oakland, CA 94612

The name, address, and telephone number of plaintiff's attorney, or plaintiff without an attorney, is:
(El nombre, la dirección y el número de teléfono del abogado del demandante, o del demandante que no tiene abogado, es):
Parviz Darabi, Esq. SBN209021
500 Airport Blvd., Suite 410
Burlingame, CA 94010
LAW OFFICES OF PARVIZ DARABI
Tel: (650) 343-5357 / Fax: (650) 343-5391

DATE: *(Fecha)* AUG - 2 2021 Chad Finke
Clerk, by *(Secretario)* K. Ghee, Deputy *(Adjunto)*
(For proof of service of this summons, use Proof of Service of Summons *(form POS-010).)*
(Para prueba de entrega de esta citación use el formulario Proof of Service of Summons, *(POS-010)).*

[SEAL]

NOTICE TO THE PERSON SERVED: You are served
1. ☐ as an individual defendant.
2. ☐ as the person sued under the fictitious name of *(specify):*
3. ☒ on behalf of *(specify):* ALOM TECHNOLOGIES CORPORATION
   under: ☒ CCP 416.10 (corporation) ☐ CCP 416.60 (minor)
   ☐ CCP 416.20 (defunct corporation) ☐ CCP 416.70 (conservatee)
   ☐ CCP 416.40 (association or partnership) ☐ CCP 416.90 (authorized person)
   ☐ other *(specify):*
4. ☒ by personal delivery on *(date):* August 6th 2021

Form Adopted for Mandatory Use
Judicial Council of California
SUM-100 [Rev. July 1, 2009]
CEB Essential Forms
SUMMONS
Code of Civil Procedure §§ 412.20, 465
www.courtinfo.ca.gov

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):
Parviz Darabi, Esq. SBN209021
LAW OFFICES OF PARVIZ DARABI
500 Airport Blvd., Suite 410
Burlingame, CA 94010
TELEPHONE NO.: (650) 343-5357 FAX NO.: (650) 343-5391
ATTORNEY FOR (Name): Plaintiff

FOR COURT USE ONLY

K. Ghee

SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda
STREET ADDRESS: 1225 Fallon Street
MAILING ADDRESS:
CITY AND ZIP CODE: Oakland, CA 94612
BRANCH NAME: Civil /Unlimited Jurisdiction

CASE NAME: ORDONEZ vs. SILICON VALLEY TECHNICAL STAFFING, et. al.

CIVIL CASE COVER SHEET
☑ Unlimited (Amount demanded exceeds $25,000) ☐ Limited (Amount demanded is $25,000 or less)

Complex Case Designation
☐ Counter ☐ Joinder
Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)

CASE NUMBER: RG 21107257

JUDGE:

DEPT.:

Items 1-6 below must be completed (see instructions on page 2).

1. Check one box below for the case type that best describes this case:

Auto Tort
☐ Auto (22)
☐ Uninsured motorist (46)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort
☐ Asbestos (04)
☐ Product liability (24)
☐ Medical malpractice (45)
☐ Other PI/PD/WD (23)

Non-PI/PD/WD (Other) Tort
☐ Business tort/unfair business practice (07)
☐ Civil rights (08)
☐ Defamation (13)
☐ Fraud (16)
☐ Intellectual property (19)
☐ Professional negligence (25)
☐ Other non-PI/PD/WD tort (35)

Employment
☑ Wrongful termination (36)
☐ Other employment (15)

Contract
☐ Breach of contract/warranty (06)
☐ Rule 3.740 collections (09)
☐ Other collections (09)
☐ Insurance coverage (18)
☐ Other contract (37)

Real Property
☐ Eminent domain/inverse condemnation (14)
☐ Wrongful eviction (33)
☐ Other real property (26)

Unlawful Detainer
☐ Commercial (31)
☐ Residential (32)
☐ Drugs (38)

Judicial Review
☐ Asset forfeiture (05)
☐ Petition re: arbitration award (11)
☐ Writ of mandate (02)
☐ Other judicial review (39)

Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400-3.403)
☐ Antitrust/Trade regulation (03)
☐ Construction defect (10)
☐ Mass tort (40)
☐ Securities litigation (28)
☐ Environmental/Toxic tort (30)
☐ Insurance coverage claims arising from the above listed provisionally complex case types (41)

Enforcement of Judgment
☐ Enforcement of judgment (20)

Miscellaneous Civil Complaint
☐ RICO (27)
☐ Other complaint *(not specified above)* (42)

Miscellaneous Civil Petition
☐ Partnership and corporate governance (21)
☐ Other petition *(not specified above)* (43)

2. This case ☐ is ☑ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
   a. ☐ Large number of separately represented parties
   b. ☐ Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
   c. ☐ Substantial amount of documentary evidence
   d. ☐ Large number of witnesses
   e. ☐ Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
   f. ☐ Substantial postjudgment judicial supervision
3. Remedies sought *(check all that apply)*: a. ☑ monetary b. ☐ nonmonetary; declaratory or injunctive relief c. ☐ punitive
4. Number of causes of action *(specify)*: Fourteen
5. This case ☐ is ☑ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. *(You may use form CM-015.)*

Date: 7/30/2021

Parviz Darabi, Esq.
(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE
- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for stetistical purposes only.

Form Adopted for Mandatory Use Judicial Council of California CM-010 [Rev. July 1, 2007]
CEB ceb.com | Essential Forms

CIVIL CASE COVER SHEET

Cal. Rules of Court, rules 2.30, 3.220, 3.400-3.403, 3.740; Cal. Standards of Judicial Administration, std. 3.10
www.courtinfo.ca.gov

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than $25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES

Auto Tort
- Auto (22)-Personal Injury/Property Damage/Wrongful Death
- Uninsured Motorist (46) *(if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto)*

Other PI/PD/WD (Personal Injury/ Property Damage/Wrongful Death) Tort
- Asbestos (04)
  - Asbestos Property Damage
  - Asbestos Personal Injury/ Wrongful Death
- Product Liability *(not asbestos or toxic/environmental)* (24)
- Medical Malpractice (45)
  - Medical Malpractice-Physicians & Surgeons
  - Other Professional Health Care Malpractice
- Other PI/PD/WD (23)
  - Premises Liability (e.g., slip and fall)
  - Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
  - Intentional Infliction of Emotional Distress
  - Negligent Infliction of Emotional Distress
  - Other PI/PD/WD

Non-PI/PD/WD (Other) Tort
- Business Tort/Unfair Business Practice (07)
- Civil Rights (e.g., discrimination, false arrest) *(not civil harassment)* (08)
- Defamation (e.g., slander, libel) (13)
- Fraud (16)
- Intellectual Property (19)
- Professional Negligence (25)
  - Legal Malpractice
  - Other Professional Malpractice *(not medical or legal)*
- Other Non-PI/PD/WD Tort (35)

Employment
- Wrongful Termination (36)
- Other Employment (15)

Contract
- Breach of Contract/Warranty (06)
  - Breach of Rental/Lease Contract *(not unlawful detainer or wrongful eviction)*
  - Contract/Warranty Breach-Seller Plaintiff *(not fraud or negligence)*
  - Negligent Breach of Contract/ Warranty
  - Other Breach of Contract/Warranty
- Collections (e.g., money owed, open book accounts) (09)
  - Collection Case-Seller Plaintiff
  - Other Promissory Note/Collections Case
- Insurance Coverage *(not provisionally complex)* (18)
  - Auto Subrogation
  - Other Coverage
- Other Contract (37)
  - Contractual Fraud
  - Other Contract Dispute

Real Property
- Eminent Domain/Inverse Condemnation (14)
- Wrongful Eviction (33)
- Other Real Property (e.g., quiet title) (26)
  - Writ of Possession of Real Property
  - Mortgage Foreclosure
  - Quiet Title
  - Other Real Property *(not eminent domain, landlord/tenant, or foreclosure)*

Unlawful Detainer
- Commercial (31)
- Residential (32)
- Drugs (38) *(if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential)*

Judicial Review
- Asset Forfeiture (05)
- Petition Re: Arbitration Award (11)
- Writ of Mandate (02)
  - Writ-Administrative Mandamus
  - Writ-Mandamus on Limited Court Case Matter
  - Writ-Other Limited Court Case Review
- Other Judicial Review (39)
  - Review of Health Officer Order
  - Notice of Appeal-Labor Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400-3.403)
- Antitrust/Trade Regulation (03)
- Construction Defect (10)
- Claims Involving Mass Tort (40)
- Securities Litigation (28)
- Environmental/Toxic Tort (30)
- Insurance Coverage Claims *(arising from provisionally complex case type listed above)* (41)

Enforcement of Judgment
- Enforcement of Judgment (20)
  - Abstract of Judgment (Out of County)
  - Confession of Judgment *(non-domestic relations)*
  - Sister State Judgment
  - Administrative Agency Award *(not unpaid taxes)*
  - Petition/Certification of Entry of Judgment on Unpaid Taxes
  - Other Enforcement of Judgment Case

Miscellaneous Civil Complaint
- RICO (27)
- Other Complaint *(not specified above)* (42)
  - Declaratory Relief Only
  - Injunctive Relief Only *(non-harassment)*
  - Mechanics Lien
  - Other Commercial Complaint Case *(non-tort/non-complex)*
  - Other Civil Complaint *(non-tort/non-complex)*

Miscellaneous Civil Petition
- Partnership and Corporate Governance (21)
- Other Petition *(not specified above)* (43)
  - Civil Harassment
  - Workplace Violence
  - Elder/Dependent Adult Abuse
  - Election Contest
  - Petition for Name Change
  - Petition for Relief from Late Claim
  - Other Civil Petition

Superior Court of California, County of Alameda
Alternative Dispute Resolution (ADR) Information Packet

The person who files a civil lawsuit (plaintiff) must include the ADR Information Packet with the complaint when serving the defendant. Cross complainants must serve the ADR Information Packet on any new parties named to the action.

The Court *strongly encourages* the parties to use some form of ADR before proceeding to trial. You may choose ADR by:

- Indicating your preference on Case Management Form CM-110;
- Filing the Stipulation to ADR and Delay Initial Case Management Conference for 90 Days (a local form included with the information packet); or
- Agree to ADR at your Initial Case Management Conference.

QUESTIONS? Call (510) 891-6055. Email adrprogram@alameda.courts.ca.gov
Or visit the court's website at http://www.alameda.courts.ca.gov/adr

What Are The Advantages Of Using ADR?

- ***Faster*** –Litigation can take years to complete but ADR usually takes weeks or months.
- ***Cheaper*** – Parties can save on attorneys' fees and litigation costs.
- ***More control and flexibility*** – Parties choose the ADR process appropriate for their case.
- ***Cooperative and less stressful*** – In mediation, parties cooperate to find a mutually agreeable resolution.
- ***Preserve Relationships*** – A mediator can help you effectively communicate your interests and point of view to the other side. This is an important benefit when you want to preserve a relationship.

What Is The Disadvantage Of Using ADR?

- ***You may go to court anyway*** – If you cannot resolve your dispute using ADR, you may still have to spend time and money resolving your lawsuit through the courts.

What ADR Options Are Available?

- ***Mediation*** – A neutral person (mediator) helps the parties communicate, clarify facts, identify legal issues, explore settlement options, and agree on a solution that is acceptable to all sides.
  - **Court Mediation Program**: Mediators do not charge fees for the first two hours of mediation. If parties need more time, they must pay the mediator's regular fees.

Some mediators ask for a deposit before mediation starts which is subject to a refund for unused time.

- **Private Mediation**: This is mediation where the parties pay the mediator's regular fees and may choose a mediator outside the court's panel.

- ***Arbitration*** – A neutral person (arbitrator) hears arguments and evidence from each side and then decides the outcome of the dispute. Arbitration is less formal than a trial and the rules of evidence are often relaxed. Arbitration is effective when the parties want someone other than themselves to decide the outcome.

  - **Judicial Arbitration Program** (non-binding): The judge can refer a case or the parties can agree to use judicial arbitration. The parties select an arbitrator from a list provided by the court. If the parties cannot agree on an arbitrator, one will be assigned by the court. There is no fee for the arbitrator. The arbitrator must send the decision (award of the arbitrator) to the court. The parties have the right to reject the award and proceed to trial.

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Mediation Service Programs In Alameda County

Low cost mediation services are available through non-profit community organizations. Trained volunteer mediators provide these services. Contact the following organizations for more information:

SEEDS Community Resolution Center
2530 San Pablo Avenue, Suite A, Berkeley, CA 94702-1612
Telephone: (510) 548-2377 Website: www.seedscrc.org
Their mission is to provide mediation, facilitation, training and education programs in our diverse communities – **S**ervices that **E**ncourage **E**ffective **D**ialogue and **S**olution-making.

Center for Community Dispute Settlement
291 McLeod Street, Livermore, CA 94550
Telephone: (925) 373-1035 Website: www.trivalleymediation.com
CCDS provides services in the Tri-Valley area for all of Alameda County.

For Victim/Offender Restorative Justice Services
Catholic Charities of the East Bay: Oakland
433 Jefferson Street, Oakland, CA 94607
Telephone: (510) 768-3100 Website: www.cceb.org
Mediation sessions involve the youth, victim, and family members work toward a mutually agreeable restitution agreement.

ALA ADR-001

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address):	FOR COURT USE ONLY
TELEPHONE NO: FAX NO. (Optional): E-MAIL ADDRESS (Optional): ATTORNEY FOR (Name):	
SUPERIOR COURT OF CALIFORNIA, ALAMEDA COUNTY STREET ADDRESS: MAILING ADDRESS: CITY AND ZIP CODE: BRANCH NAME:	
PLAINTIFF/PETITIONER: DEFENDANT/RESPONDENT:	
STIPULATION TO ATTEND ALTERNATIVE DISPUTE RESOLUTION (ADR) AND DELAY INITIAL CASE MANAGEMENT CONFERENCE FOR 90 DAYS	CASE NUMBER:

INSTRUCTIONS: All applicable boxes must be checked, and the specified information must be provided.

This stipulation is effective when:

- All parties have signed and filed this stipulation with the Case Management Conference Statement at least 15 days before the initial case management conference.
- A copy of this stipulation has been received by the ADR Program Administrator, 24405 Amador Street, Hayward, CA 94544 or Fax to (510) 267-5727.

1. Date complaint filed: _____. An **Initial Case Management Conference** is scheduled for:

   Date: Time: Department:

2. Counsel and all parties certify they have met and conferred and have selected the following ADR process (*check one*):

   ☐ Court mediation ☐ Judicial arbitration
   ☐ Private mediation ☐ Private arbitration

3. All parties agree to complete ADR within 90 days and certify that:
   a. No party to the case has requested a complex civil litigation determination hearing;
   b. All parties have been served and intend to submit to the jurisdiction of the court;
   c. All parties have agreed to a specific plan for sufficient discovery to make the ADR process meaningful;
   d. Copies of this stipulation and self-addressed stamped envelopes are provided for returning endorsed filed stamped copies to counsel and all parties;
   e. Case management statements are submitted with this stipulation;
   f. All parties will attend ADR conferences; and,
   g. The court will not allow more than 90 days to complete ADR.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date:

_____ ▶ _____

(TYPE OR PRINT NAME) (SIGNATURE OF PLAINTIFF)

Date:

_____ ▶ _____

Form Approved for Mandatory Use
Superior Court of California
County of Alameda
ALA ADR-001 [New January 1, 2010]

STIPULATION TO ATTEND ALTERNATIVE DISPUTE RESOLUTION (ADR) AND DELAY INITIAL CASE MANAGEMENT CONFERENCE FOR 90 DAYS

Cal. Rules of Court, rule 3.221(e)(4)

(TYPE OR PRINT NAME) (SIGNATURE OF ATTORNEY FOR PLAINTIFF)

ALA ADR-001

PLAINTIFF/PETITIONER: DEFENDANT/RESPONDENT:	CASE NUMBER.:

Date:

_____ ▶ _____

(TYPE OR PRINT NAME) (SIGNATURE OF DEFENDANT)

Date:

_____ ▶ _____

(TYPE OR PRINT NAME) (SIGNATURE OF ATTORNEY FOR DEFENDANT)

Form Approved for Mandatory Use
Superior Court of California
County of Alameda
ALA ADR-001 [New January 1, 2010]

STIPULATION TO ATTEND ALTERNATIVE DISPUTE RESOLUTION (ADR) AND DELAY INITIAL CASE MANAGEMENT CONFERENCE FOR 90 DAYS

Cal. Rules of Court, rule 3.221(a)(4)

Law Offices of Parviz Darabi
Attn: Darabi, Parviz
500 Airport Blvd., Ste. 410
Burlingame, CA 94010____

Superior Court of California, County of Alameda

Gonzalez **Plaintiff/Petitioner(s)** **VS.** Silicon Valley Technical Staffing **Defendant/Respondent(s)** (Abbreviated Title)	No. RG21107257 **NOTICE OF CASE MANAGEMENT CONFERENCE AND ORDER** Unlimited Jurisdiction

TO ALL PARTIES AND TO THEIR ATTORNEYS OF RECORD:
Notice is given that a Case Management Conference has been scheduled as follows:

Date: **12/15/2021** Time: **09:00 AM**	Department: **25** Location: **Administration Building** **1221 Oak Street, Oakland CA 94612** Internet: **www.alameda.courts.ca.gov**	Judge: **James Reilly** Clerk: **Pamela Greene** Clerk telephone: **(510) 267-6941** E-mail: **Dept25@alameda.courts.ca.gov** Fax: **(510) 891-5346**

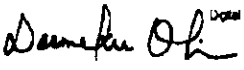
ORDERS

1. **Plaintiff** must:
   a. **Serve** all named defendants and file proofs of service on those defendants with the court within 60 days of the filing of the complaint (Cal. Rules of Court, 3.110(b)); and
   b. **Give notice** of this conference to all other parties and file proof of service.
2. **Defendant must** respond as stated on the summons.
3. **All parties who have appeared before the date of the conference** must:
   a. **Meet and confer**, in person or by telephone as required by Cal. Rules of Court, rule 3.724;
   b. **File and serve** a completed *Case Management Statement* on Form CM-110 at least **15** days before the Case Management Conference (Cal. Rules of Court, rule 3.725); and
   c. **Post jury fees** as required by Code of Civil Procedure section 631.
4. If you do not follow the orders above, the court may issue an order to show cause why you should not be sanctioned under Cal. Rules of Court, rule 2.30. Sanctions may include monetary sanctions, striking pleadings or dismissal of the action.
5. You are further ordered to appear in person or through your attorney of record at the Case Management Conference noticed above. You must be thoroughly familiar with the case and fully authorized to proceed. You may be able to appear at Case Management Conferences by telephone. Contact CourtCall, an independent vendor, at least three business days before the scheduled conference. Call 1-888-882-6878, or fax a service request to (888) 882-2946. The vendor charges for this service.
6. You may file *Case Management Conference Statements* by E-Delivery. Submit them directly to the E-Delivery Fax Number (510) 267-5732. No fee is charged for this service. For further information, go to *www.alameda.courts.ca.gov/ff*.
7. The judge may place a *Tentative Case Management Order* in your case's on-line register of actions before the conference. This order may establish a discovery schedule, set a trial date or refer the case to Alternate Dispute Resolution, such as mediation or arbitration. Check the website of each assigned department for procedures regarding tentative case management orders at *www.alameda.courts.ca.gov/dc*.

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice of Hearing by placing copies in envelopes addressed as shown hereon and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 08/04/2021.

By 

Deputy Clerk

Superior Court of California, County of Alameda

Notice of Assignment of Judge for All Purposes

Case Number: RG21107257
Case Title: Gonzalez VS Silicon Valley Technical Staffing
Date of Filing: 08/02/2021

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Pursuant to Rule 3.734 of the California Rules of Court and Title 3 Chapter 2 of the Local Rules of the Superior Court of California, County of Alameda, this action is hereby assigned by the Presiding Judge for all purposes to:

Judge:	**James Reilly**
Department:	**25**
Address:	**Administration Building** **1221 Oak Street** **Oakland CA 94612**
Phone Number:	**(510) 267-6941**
Fax Number:	**(510) 891-5346**
Email Address:	**Dept25@alameda.courts.ca.gov**

Under direct calendaring, this case is assigned to a single judge for all purposes including trial.

Please note: In this case, any challenge pursuant to Code of Civil Procedure section 170.6 must be exercised within the time period provided by law. (See Code Civ. Proc. §§ 170.6, subd. (a)(2) and 1013.)

NOTICE OF NONAVAILABILITY OF COURT REPORTERS: Effective June 4, 2012, the court will not provide a court reporter for civil law and motion hearings, any other hearing or trial in civil departments, or any afternoon hearing in Department 201 (probate). Parties may arrange and pay for the attendance of a certified shorthand reporter. In limited jurisdiction cases, parties may request electronic recording.

Amended Local Rule 3.95 states: "Except as otherwise required by law, in general civil case and probate departments, the services of an official court reporter are not normally available. For civil trials, each party must serve and file a statement before the trial date indicating whether the party requests the presence of an official court reporter."

IT IS THE DUTY OF EACH PLAINTIFF AND CROSS COMPLAINANT TO SERVE A COPY OF THIS NOTICE IN ACCORDANCE WITH LOCAL RULES.

General Procedures

Following assignment of a civil case to a specific department, all pleadings, papers, forms, documents and writings can be submitted for filing at either Civil Clerk's Office, located at the René C. Davidson Courthouse, Room 109, 1225 Fallon Street, Oakland, California, 94612, and the Hayward Hall of Justice, 24405 Amador Street, Hayward, California, 94544. All documents, with the exception of the original summons and the original civil complaint, shall have clearly typed on the face page of each document, under the case number, the following:

ASSIGNED FOR ALL PURPOSES TO
JUDGE James Reilly
DEPARTMENT 25

All parties are expected to know and comply with the Local Rules of this Court, which are available on the court's website at: http://www.alameda.courts.ca.gov/Pages.aspx/Local-Rules(1) and with the California Rules of Court, which are available at www.courtinfo.ca.gov.

Parties must meet and confer to discuss the effective use of mediation or other alternative dispute processes (ADR) prior to the Initial Case Management Conference. The court encourages parties to file a "Stipulation to Attend ADR and Delay Initial Case Management Conference for 90 Days". Plaintiff received that form in the ADR information package at the time the complaint was filed. The court's website also contains this form and other ADR information. If the parties do not stipulate to attend ADR, the parties must be prepared to discuss referral to ADR at the Initial Case Management Conference.

Self-represented litigants must also comply with the rules cited above. All references to "counsel" in this Order apply equally to self-represented litigants. The Court maintains a Self-Help Center at the Hayward Hall of Justice, 24405 Amador Street, 1st Floor (Department 501), Hayward, CA 94544.

With the exception of Case Management Statements, please submit a courtesy copy of all filed documents directly to Dept. 25.

Schedule for Department 25

The following scheduling information is subject to change at any time, without notice. Please contact the department at the phone number or email address noted above if you have questions.

- Trials generally are held: Monday through Friday 9:30 a.m. to 4:30 p.m. A pretrial conference will be set two to three weeks before the trial.
- Case Management Conferences are held: Monday through Friday at 9:00 a.m. Timely filed and complete Case Management Statements may eliminate the need for an in-person conference by allowing the Court to publish a Tentative Case Management Order.
- Law and Motion matters are heard: Wednesday and Friday at 9:00 a.m.
- Settlement Conferences are heard: Settlement Conferences are set by the Judge.
- Ex Parte matters are heard: Wednesday and Friday at 9:00 a.m.

- Department 25 has opted out of the Informal Discovery Conference protocol pursuant to Local Rule 3.31 and CCP section 2016.080. Please email the department (dept25@alameda.courts.ca.gov) to reserve a hearing date for a discovery motion. When requesting a reservation number, note the nature of the motion, the party you represent, and two or three proposed hearing dates (on a Wednesday or Friday at 9:00), factoring in the time required for statutory notice. No discovery motion shall be filed without prior serious efforts to resolve it.
- Limited hearings are available for summary judgments, preliminary injunctions and other time-sensitive motions.

Law and Motion Procedures

To obtain a hearing date for a Law and Motion or ex parte matter, parties must contact the department as follows:

- Motion Reservations
  Email: Dept25@alameda.courts.ca.gov
  Phone: (510) 267-6941

  The Court requests that reservations be made by e-mail to avoid disrupting courtroom proceedings.

- Ex Parte Matters
  Email: Dept25@alameda.courts.ca.gov
  Phone: (510) 267-6941

Tentative Rulings

The court may issue tentative rulings in accordance with the Local Rules. Tentative rulings will become the Court's order unless contested in accordance with the Local Rules. Tentative rulings will be available at:

- Website: www.alameda.courts.ca.gov/domainweb, Calendar Information for Dept. 25
- Phone: 1-866-223-2244

Dated: 08/03/2021

Facsimile

Presiding Judge,
Superior Court of California, County of Alameda

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as shown on the attached Notice of Initial Case Management Conference and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 08/04/2021

By Daniela Oli Digital

Deputy Clerk

PARVIZ DARABI – Bar No. 209021
LAW OFFICES OF PARVIZ DARABI
500 Airport Blvd., Suite 410
Burlingame, CA 94010
Telephone: (650) 343-5357
Facsimile: (650) 343-5391

Attorney for Plaintiff,
DEBLIN MATEO GONZALEZ ORDONEZ

K. Ghee

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA
UNLIMITED JURISDICTION

DEBLIN MATEO GONZALEZ ORDONEZ, an individual;

PLAINTIFF,

vs.

SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC; ALOM TECHNOLOGIES CORPORATION, a California Corporation; and DOES 1-30, inclusive,

DEFENDANTS.

Case No.: RG 21107257

COMPLAINT FOR DAMAGES:

1. **Failure to Pay Overtime Wages**: Violation of LC§§ 510, 1194, 1198 and IWC Wage Order "Hours and Days of Work" Section;
2. **Failure to Pay Minimum Wages and Secret Underpayment of Wages**: Violation of LC§§ 223, 1197, 1198 and IWC Wage Order "Hours and Days of Work" and "Minimum Wage" Sections;
3. **Failure to Pay Minimum Wages:** Violation of Labor Code §1194.2;
4. **Failure to Indemnify for Expenses and Losses in Discharging Duties:** Violation of LC§§ 2802;
5. **Failure to Provide Meal Periods**: Violation of LC§§ 226.7, 512, and IWC Wage Order "Meal Periods" Section;
6. **Failure to Provide Rest Periods**: Violation of LC§ 226.7 and IWC Wage Order "Rest Periods" Section;
7. **Failure to Provide and Maintain Accurate Itemized Wage Statements**: Violation of LC§§ 226, 1174, 1198 and IWC Wage Order "Records" Section;
8. **Failure to Pay Wages Due Upon Termination**: Violation of LC§§ 201, 202, 203 and IWC Wage Order;

9. **Unfair Business Practice:** Violation of Business & Professions Code §§ 17200, et seq.;
10. **Retaliation:** Violation of Labor Code §232.5;
11. **Wrongful Termination:** In Violation of Public Policy;
12. **Wrongful Termination [FEHA]**: Violation of Gov. Code §§12900 and 12940 et seq.;
13. **Failure to Provide Reasonable Accommodation [FEHA]:** Violation of Cal. Gov. Code §§12940 (m), 12926(p) and Cal. Code Regs., Title 2 §11068;
14. **Failure to Engage in the Interactive Process [FEHA]:** Violation of Cal. Gov. Code §12940 (n);

PLAINTIFF DEMANDS JURY TRIAL

Plaintiff DEBLIN MATEO GONZALEZ ORDONEZ ("PLAINTIFF"), an individual, brings this action against defendant SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC. ("SILICON VALLEY STAFFING"); ALOM TECHNOLOGIES CORPORATION, a California Corporation, ("ALOM"), [collectively ("DEFENDANTS")], and DOES 1-30 and alleges as follows:

JURISDICTION AND VENUE

1. This court has jurisdiction over this action and the DEFENDANTS pursuant to California Code of Civil Procedure § 410.10. This is a civil action wherein the matter in controversy, exclusive of interest and costs, exceeds the jurisdictional minimum of the Court. DEFENDANTS, during times relevant to this action, conducted substantial, systematic and continuous commercial activities in California.

2. Venue is proper in this judicial district pursuant to California Code of Civil Procedure §§ 395 (a) and 395.5, as the acts and omissions which are the subject of this Complaint occurred in the County of ALAMEDA in the State of California. Each DEFENDANTS exists and does business under the laws of the State of California with substantial business contacts and engagements in ALAMEDA

County and/or a significant place of business there. During the time period relevant to this Complaint, each of the DEFENDANTS either owned property, maintained an office, transacted business, engaged in financial operations, had an agent or agents within the County of ALAMEDA, and/or was otherwise found within the County of ALAMEDA and each of the DEFENDANTS is within the jurisdiction of this Court for purposes of service of process.

PARTIES

3. During times relevant to this Complaint, PLAINTIFF was employed by the DEFENDANTS to perform services for a wage in the county of ALAMEDA, State of California and for a corporation headquartered in the county of ALAMEDA, State of California.

4. PLAINTIFF is informed and believes, and on such information and belief alleges that ALOM is and at all times relevant herein was a company in the business of producing and delivering orders to customers registered and authorized to transact business in California under Corporate no. C2012931 with its principal place of business located in California, within the County of ALAMEDA, known as 48105 Warm Springs Blvd., Fremont, California 95439. During the time period relevant to this Complaint, ALOM employed PLAINTIFF and exercised control over PLAINTIFF'S wages, hours, and working conditions. PLAINTIFF alleges, on information and belief, that at all relevant times herein, ALOM controlled, and/or managed the day-to-day operations and activities at its business through its authorized agents, supervisors/managers, including Dario [last name unknown] ("DARIO"); Manpreet [last name unknown] ("MANPREET"); and Juanita Macias ("JUANITA"), among others.

5. PLAINTIFF is informed and believes, and on that basis, alleges that Defendant, SILICON VALLEY STAFFING, is and at all relevant times herein was a company in the business of providing services to other businesses, and who is registered and authorized to transact business in California. PLAINTIFF is informed and believes, and on that basis, alleges that SILICON VALLEY STAFFING, was retained by ALOM during the time period to provide payment of wages to PLAINTIFF, on behalf of ALOM, in compensation for PLAINTIFF's labor, while ALOM retained control over the wages, hours, or working conditions of PLAINTIFF and continued to directly manage and supervise the daily work of

PLAINTIFF during the entire period of PLAINTIFF'S employment with ALOM. While PLAINTIFF lacks evidentiary support at the present time to support these allegations, he is informed and believes these alleged facts are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

6. PLAINTIFF is informed and believes and on such information and belief alleges, at all relevant times herein, SILICON VALLEY STAFFING and ALOM, were "joint employer" of PLAINTIFF and jointly liable for employment law violations within the meaning of the California Industrial Welfare Commission ("IWC") and California courts, wherein ALOM, structured a "straw men" arrangement to avoid liability and reduce labor costs by contracting with various human resource management /staffing agencies, including SILICON VALLEY STAFFING to hire and pay workers, and ALOM directly or indirectly, or through its authorized agents, DARIO, MANPREET, JUANITA, or any other person, employed and exercised full control over the wages, hours, or working conditions of its employees, including without limitation PLAINTIFF. PLAINTIFF is further informed, believes and thereon alleges that each of the DEFENDANTS herein gave consent to, ratified, and/or authorized the acts alleged herein as to each of the remaining DEFENDANTS. While PLAINTIFF lacks evidentiary support at the present time to support these allegations, he is informed and believes these alleged facts are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.

7. PLAINTIFF is informed and believes, and on that basis alleges that at all material times herein, DEFENDANTS were continuously an "employer" within the meaning of FEHA [Government Code § 12926(d)] by consistently employing five (5) or more employees.

8. At all times relevant herein, DEFENDANTS, by and through acts of its authorized agents, including but not limited to DARIO, MANPREET, and JUANITA, employed and exercised control over the wages, hours, and working conditions of its employees, including PLAINTIFF. At all times relevant herein, DARIO, MANPREET, and JUANITA were under the direct supervision, employment, agency and control of DEFENDANTS.

9. PLAINTIFF is informed and believes, and on that basis alleges that at all times relevant

hereto, DEFENDANTS (a) placed DARIO, MANPREET, and JUANITA, among others, in a position to supervise DEFENDANTS' day-to-day business operations and the work performances of their respective employees, including PLAINTIFF; and (b) empowered DARIO, MANPREET, and JUANITA, among others, to take tangible employment actions against PLAINTIFF to effect a significant change in PLAINTIFF'S employment status, including but not limited to actions substantially bearing on PLAINTIFF'S schedule and assignments, reported work hours, receipt of wages, record of disciplinary action, receipt of reasonable accommodations (or lack thereof), and employment status (*i.e.* hiring and termination). In their respective roles as PLAINTIFF'S supervisor/manager, and as authorized agents for DEFENDANTS, DARIO, MANPREET, and JUANITA and others exercised unique authority over PLAINTIFF. While PLAINTIFF lacks evidentiary support at the present time to support these allegations, he is informed and believes these alleged facts are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery. At all times material to this Complaint, DARIO, MANPREET, and JUANITA and others engaged in the conduct herein alleged and were each acting within the scope of employment and authority DEFENDANTS as PLAINTIFF'S supervisor/manager within the meaning of the California Fair Employment and Housing Act, Government Code Section 12940, *et seq.* ("FEHA").

10. The true names, capacities, relationships and extent of participation in the conduct alleged herein of the DEFENDANTS named as DOES 1 through 30, inclusive, are presently unknown to PLAINTIFF, but PLAINTIFF is informed and believes, and thereon alleges, that said DEFENDANTS are legally responsible for the wrongful conduct alleged herein and therefore sue these DEFENDANTS by such fictitious names. PLAINTIFF will amend this complaint when their true names and capabilities are ascertained.

11. PLAINTIFF is informed and believes, and thereon alleges, that each DEFENDANTS – whether named or fictitious, directly or indirectly, or through agents or other persons – engaged PLAINTIFF and exercised control over PLAINTIFF'S wages, hours, and/or working conditions.

12. PLAINTIFF is informed and believes, and thereon alleges, that each DEFENDANT

acted and/or ratified in all respects pertinent to this action as the agent of the other DEFENDANTS; PLAINTIFF is informed and believes, and thereon alleges, that each DEFENDANTS carried out a joint scheme, business plan or policy in all respects pertinent hereto, and the acts of each DEFENDANT is legally attributable to the other DEFENDANTS.

PRE-LITIGATION COMPLAINTS, CLAIM FILINGS, AND DISPOSITIONS

13. PLAINTIFF exhausted his administrative remedies under the California Fair Employment and Housing Act. On or about **July 26, 2021**. PLAINTIFF filed the charges of hostile work environment, wrongful termination, discrimination and retaliation against DEFENDANTS. On **July 26, 2021**, the Department of Fair Housing and Employment issued the Notice of Case Closure/Right-to-Sue Letter. A Copy of the Complaint and Notice of Right to Sue is attached hereto, as **Exhibit "1".**

FACTUAL ALLEGATIONS

14. PLAINTIFF began working for the DEFENDANTS around March 2019 and continued through and on or about February 24, 2021, when DEFENDANTS fired PLAINTIFF.

15. At all times relevant hereto, and during his entire period of employment with DEFENDANTS, PLAINTIFF fulfilled the duties of a full-time non-exempt employee, within the meaning of the Industrial Welfare Commission ("IWC") Order, to perform routine duties for DEFENDANTS, subject to the laws of the State of California, for the payment of wages as set-forth in the California Labor Code, and was covered under one or more statutes, regulations and Wage Orders of the IWC, and Division of Labor Standards Enforcement ("DLSE").

16. The applicable Wage Order defines "employer" as any person "who directly or indirectly, or through an agent, for any other person, employs or exercises control over the wages, hours, or working conditions of any person."

17. During the time period relevant to this Complaint, DEFENDANTS were an employer of PLAINTIFF in that DEFENDANTS employed PLAINTIFF to provide services for wages and exercised control over PLAINTIFF'S wages, hours, and working conditions, as defined and regulated by the Labor Code, the IWC Wage Order, California common law, and within the meaning of FEHA.

18. DEFENDANTS required PLAINTIFF to follow the date/time schedules devised by its supervisors (including but not limited to DARIO, MANPREET, and JUANITA) and perform work at the locations designated by its supervisors/managers (including but not limited to DARIO, MANPREET, and JUANITA). At all times, PLAINTIFF made his best efforts to adhere to the strict standards, policies, and practices established by DEFENDANTS; at all times, DEFENDANTS, by its supervisors (including but not limited to DARIO, MANPREET, and JUANITA, carried out strict oversight with respect to the minute details of PLAINITFF'S daily duties and Plaintiff's adherence to that DEFENDANTS' strict standards, policies, and practices. PLAINTIFF lacked authority or discretion to exercise independent judgment beyond the strict standards, policies, practices, schedules, assignments, and duties set forth by DEFENDANTS.

19. DEFENDANTS' uniform practices and/or treatment of PLAINTIFF required that PLAINTIFF frequently work regular and overtime hours without compensation. Throughout the time period relevant to this Complaint, PLAINTIFF often worked beyond eight (8) hours per day and/or (40) hours per week without legally-required compensation for all of that time, let alone at the overtime rate for all of those hours. Among other things that occurred: (a) one or more of DEFENDANTS' authorized agents instructed PLAINTIFF to perform work "off-the-clock" prior to, during and/or subsequent to his scheduled shift; (b) one or more of each of the DEFENDANTS' authorized agents required PLAINTIFF to perform essential job functions while he was punched-out for his meal, such that PLAINTIFF performed work "off-the-clock." In addition, DEFENDANTS routinely deprived PLAINTIFF of his rightful wages, including overtime pay. On information and belief, PLAINTIFF alleges that DEFENDANTS had the ability to monitor and did monitor the hours worked by PLAINTIFF; DEFENDANTS, therefore, knew or should have known that the PLAINTIFF routinely worked substantial time without compensation, let alone at an overtime rate.

20. During the time period relevant to this Complaint, DEFENDANTS failed to pay PLAINTIFF for all hours worked and paid PLAINTIFF a lower wage than contractually promised and

legally required. At all times relevant to this Complaint, DEFENDANTS directly and/or indirectly paid PLAINTIFF less than minimum wage for all times suffered or permitted to work for DEFENDANTS, particularly when evaluating the PLAINTIFF'S hourly wage against his actual work hours and considering hours worked "off-the-clock." DEFENDANTS failed to satisfy minimum wage requirements by secretly paying PLAINTIFF a lower wage while purporting to pay the wage designated by agreement/contract between the parties; this occurred, *inter alia,* when DEFENDANTS failed to pay the PLAINTIFF for all hours worked, *i.e.* "off-the-clock" work that was incidental to PLAINTIFF'S daily duties and responsibilities, and DEFENDANTS routinely deprived PLAINTIFF of his rightful wages, including overtime pay.

21. At all times relevant to this Complaint, PLAINTIFF regularly worked sufficient hours to require that he be provided with off-duty meal breaks. However, DEFENDANTS lacked and/or failed to consistently implement a policy requiring that PLAINTIFF be relieved of all duty for an uninterrupted 30-minute off-duty meal period, and PLAINTIFF often lacked an opportunity for a 30-minute, uninterrupted, off-duty meal period during the first 5 hours of his shift with DEFENDANTS. DEFENDANTS, by and through one or more of its supervisors and/or managers, impeded PLAINTIFFS' ability to take an a 30-minute, uninterrupted, off-duty meal period and required PLAINTIFF to perform necessary job functions instead of allowing him the chance to take such meal breaks. Compounding matters, DEFENDANTS consistently deducted time from PLAINTIFF'S wages for an off-duty meal break – even though PLAINTIFF often did not receive a full, 30-minute off-duty meal break - and this improper deduction of time led to further unpaid hours worked, including hours beyond 8 in a day which should have been compensated at any overtime rate. Additionally, DEFENDANTS failed to provide PLAINTIFF with a second 30-minute meal break when PLAINTIFF worked ten (10) or more hours in a day.

22. At all times relevant to the Complaint, PLAINTIFF regularly worked sufficient hours to require that PLAINTIFF be provided with off-duty rest breaks. However, DEFENDANTS lacked and/or failed to consistently implement a policy requiring that PLAINTIFF be relieved of all duty for an

uninterrupted 10-minute off-duty rest period, and PLAINTIFF often lacked an opportunity for a 10-minute, uninterrupted, off-duty rest period during the course of his shift, let alone multiple off-duty rest periods on days exceeding 6 hours. DEFENDANTS, by and through its agents, including without limitation supervisors/managers, impeded PLAINTIFF'S ability to take an a 10-minute, uninterrupted, off-duty rest period and required PLAINTIFF to perform necessary job functions instead of allowing him the chance to take such rest periods.

23. At all times relevant to the Complaint, DEFENDANTS required PLAINTIFF to bear necessary job expenses and failed to indemnify or reimburse PLAINTIFF for such expenses. This includes but is not limited to: (b) the cost of cell phone service which was required of PLAINTIFF to perform his daily job duties.

24. During times relevant to the Complaint, flowing from its failures with respect to the compensation and indemnification of PLAINTIFF, as herein alleged, DEFENDANTS regularly failed to timely issue complete and accurate wage statements to PLAINTIFF. Likewise, DEFENDANTS failed to timely remit final payments in full to PLAINTIFF, who no longer works for the DEFENDANTS.

25. PLAINTIFF alleges on information and belief that DEFENDANTS' acts and omissions, as described in this Complaint, violate the Civil Code, Labor Code and the applicable Wage Order. PLAINTIFF on information and belief alleges that DEFENDANTS knew or should have known of the unlawful nature of its acts and omissions, as described in this Complaint – and that such conduct reflects a deliberate scheme to lower payroll costs and gain an unfair workforce advantage, contrary to public policy.

26. PLAINTIFF further alleges on information and belief that such acts and omissions constitute unlawful business practices and amount to policies in violation of FEHA given that they occurred in a continuing and systematic manner over a substantial period of time to the detriment of PLAINTIFF and other employees. Examples of such unlawful acts and omissions that occurred within four (4) years prior of the filing of this Complaint include, without limitation, DEFENDANTS' failure to (i) pay proper wages, including that of overtime wages, "all hours worked," "off-the-clock" hours, and

payment of wages at the rate designated by statute or by contract; (ii) indemnify and reimburse expenses incurred in discharging duties; (iii) provide all required code-compliant meal and rest breaks; (iv) pay timely wages upon termination of employment; (v) maintain accurate records and provide and maintain accurate itemized wage statements; (vi) prevent harassment, discrimination and retaliation against persons who engage in protected activities; (vii) prevent harassment, discrimination and retaliation against persons who are members of a protected class; (viii) offer reasonable accommodations of restrictions in light of employee work restrictions; and (ix) prevent discrimination and retaliation against persons who present a medical condition or disability which requires accommodation.

27. PLAINTIFF repeatedly complained to his supervisor, DARIO, MANPREET, and JUANITA, about him not being able to take his rest and lunch breaks; not being able to use his sick leave; the injuries he suffered while working for DEFENDANTS along with the pain associated with those injuries; and not being reimbursed for the use of his cell phone. However, DEFENDANTS never addressed these issues.

28. On or about February 23, 2021, PLAINTIFF injured his left shoulder and lower back while lifting a pallet weighing about 80 lbs. PLAINTIFF reported this incident to his manager, DARIO, immediately. DEFENDANTS failed to refer PLAINTIFF to see a worker's compensation clinic; open a worker's compensation claim; or provide PLAINTIFF with accommodations/modified duties. Rather than providing accommodations/modified duties to PLAINTIFF for the above injuries, DEFENDANT fired PLAINTIFF the day after his injury. PLAINTIFF is still experiencing daily pain and numbness due to the injuries referenced above.

29. DEFENDANTS failed to engage in a good-faith interactive process with PLAINTIFF to explore the accommodation of his medical condition/injury. Instead, PLAINTIFF alleges on information and belief that DEFENDANTS, by and through its respective agents, discriminated against PLAINTIFF and treated him less favorably due to his injury-related disability, work restrictions, and insistence on reasonable accommodation. PLAINTIFF's workplace injuries affected his ability to perform his duties. PLAINTIFF sought an accommodation from DEFENDANTS in order to continue to carry out the core

functions of his job without risking further injury.

30. PLAINTIFF is informed and believes that, as a result of PLAINTIFF'S status in a protected class (i.e., injury-related disability/medical condition) and engagement in multiple protected activities, as herein described and including reporting workplace safety and public health issues, DEFENDANTS, by and through one or more of its agents, discriminated against and retaliated against PLAINTIFF. PLAINTIFF asserts on information and belief that PLAINTIFF faced retaliation – specifically termination of his employment – as a direct result of (a) reporting workplace injuries and seeking medical treatment, and (b) subsequently seeking reasonable accommodations and to receive a good-faith interactive process. PLAINTIFF alleges that the aforementioned retaliation was a primary driver of PLAINTIFF's termination.

31. At all times relevant to this Complaint, DEFENDANTS maintained unlawful employment policies and practices for financial gain. During the time period relevant to this Complaint, PLAINTIFF observed, reported, and attempted to prevent unlawful conduct committed by, at the direction of and/ or under the control and supervision of each of the DEFENDANTS. This includes, without limitation: (a) complaining about a lack of proper rest and/or meals breaks; (b) complaining about unpaid hours including overtime; and (c) asserting the right to receive medical care and reasonable accommodations in conjunction with disability/medical conditions resulting from a workplace injury. Examples of such harassment, discrimination, and retaliation include, without limitation:

a) Refusing to provide PLAINTIFF with medical care for his workplace injuries;

b) Refusing to engage in an interactive dialogue with PLAINTIFF to determine what reasonable accommodations he required as a result of his workplace injuries;

c) Failing to provide PLAINTIFF with opportunities for legally-compliant meal and rest breaks;

d) Demanding that PLAINTIFF perform work off-clock;

e) Retaliating against PLAINTIFF by terminating his employment; and

f) Refusing to allow Plaintiff to use his sick leave days.

32. PLAINTIFF alleges, on information and belief, that he was targeted for termination and

terminated by DEFENDANTS – despite the fact that he had been a reliable and hardworking employee– due to his protected status (workplace injury-related medical condition/disability) and engagement in multiple protected activities. Throughout his employment, PLAINTIFF performed the duties of his work assignments in a competent and proficient manner; he was at all times ready, willing and able to perform his tasks reliably and capably.

33. PLAINTIFF alleges on information and belief that DARIO, MANPREET, and JUANITA and others acted within the scope of employment and pursuant to the authority given by DEFENDANTS as PLAINTIFF'S managers/supervisors within the meaning of FEHA – and, further, acted for their own personal motives, based on personal bias against PLAINTIFF on the basis of PLAINTIFF'S medical condition/disability, and engagement in protected activities (*i.e.* advocating for reasonable accommodation, complaining about unlawful policies and practices, reporting unsafe working conditions) – while undertaking the actions and omissions herein alleged.

FIRST CAUSE OF ACTION

Failure to Pay Wages & Overtime Wages
(Violation of Labor Code §§ 510, 1194, 1198 and
IWC Wage Order "Hours and Days of Work" Section)
(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

34. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

35. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

36. Labor Code § 510 provides in pertinent part: "Eight hours of labor constitutes a day's work. Any work in excess of 8 hours in one workday and any work in excess of 40 hours in any one workweek and the first eight hours worked on the seventh day of work in any one workweek shall be compensated at the rate of no less than one and one-half times the regular rate of pay for an employee. Any work in excess of 12 hours in one day shall be compensated at the rate of no less than twice the

regular rate of pay for an employee. In addition, any work in excess of eight hours on any seventh day of a workweek shall be compensated at the rate of no less than twice the regular rate of pay of an employee."

37. Labor Code § 1198 states: "The maximum hours of work and the standard conditions of labor fixed by the commission shall be the maximum hours of work and the standard conditions of labor for employees. The employment of any employee for longer hours than those fixed by the order or under conditions of labor prohibited by the order is unlawful."

38. The "Hours and Days of Work" section of the applicable Wage Order provides as a standard of conditions of labor that employees be paid at least the applicable overtime wage for all hours suffered or permitted to work respectively.

39. Labor Code § 1194 states "Notwithstanding any agreement to work for a lesser wage, any employee receiving less than the legal minimum wage or the legal overtime compensation applicable to the employee is entitled to recover in a civil action the unpaid balance of the full amount of his minimum wage or overtime compensation, including interest thereon, reasonable attorney's fees and costs of suit."

40. DEFENDANTS' uniform practices and/or treatment of PLAINTIFF required that PLAINTIFF frequently work regular and overtime hours without compensation. Throughout the time period relevant to this Complaint, and during PLAINTIFF'S employment period, PLAINTIFF often worked beyond eight (8) hours per day and/or (40) hours per week without legally-required compensation for all of that time, let alone at any overtime rate. Among other things that occurred: (a) one or more of DEFENDANTS' authorized agents instructed PLAINTIFF to perform work "off-the-clock" prior to, during and/or subsequent to his scheduled shift; (b) one or more of each of the DEFENDANTS' authorized agents required PLAINTIFF to perform essential job functions while he was punched-out for his meal, such that PLAINTIFF performed work "off-the-clock." In addition, DEFENDANTS routinely deprived PLAINTIFF of his rightful wages, including overtime pay. On information and belief, PLAINTIFF alleges that DEFENDANTS had the ability to monitor and did monitor the hours worked by PLAINTIFF; DEFENDANTS, therefore, knew or should have known that the PLAINTIFF routinely worked substantial time without compensation, let alone at an overtime rate.

41. During the time period relevant to this Complaint, DEFENDANTS failed to pay PLAINTIFF for all hours worked and paid PLAINTIFF a lower wage than contractually promised and legally required. At all times relevant to this Complaint, DEFENDANTS directly and/or indirectly paid PLAINTIFF less than minimum wage for all times suffered or permitted to work for DEFENDANTS, particularly when evaluating the PLAINTIFF'S hourly wage against his actual work hours and considering hours worked "off-the-clock." DEFENDANTS failed to satisfy minimum wage requirements by secretly paying PLAINTIFF a lower wage while purporting to pay the wage designated by agreement/contract between the parties; this occurred, *inter alia,* when DEFENDANTS failed to pay PLAINTIFF for all hours worked, *i.e.* "off-the-clock" work that was incidental to PLAINTIFF'S daily duties and responsibilities and DEFENDANTS routinely deprived PLAINTIFF of his rightful wages.

42. By its conduct during the applicable statutory period, including but not limited to the conduct herein described (which includes but is not limited to matters alleged on information and belief), DEFENDANTS failed and refused to pay PLAINTIFF proper compensation for all hours worked, including without limitation overtime compensation for all overtime hours worked, and in the manner required by California law, in violation of Labor Code §§ 510, 1194, and 1198 as well as the applicable Wage Order.

43. As a direct result of DEFENDANTS' violations, as herein alleged, PLAINTIFF has suffered and continues to suffer substantial losses including, but not limited, to the use and enjoyment of such wages, lost interest on such monies and expenses and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform on its obligations under state law, all to his damage in amounts according to proof at trial and within the jurisdictional limitations of this Court.

44. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §§510, 1194, 1198 and Code of Civil Procedure §§ 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at

trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

SECOND CAUSE OF ACTION

Failure to Pay Wages, Minimum Wages and Secret Underpayment of Wages
(Violation of Labor Code §§223,1197, 1198 and
IWC Wage Order "Hours and Days of Work" and "Minimum Wage" Sections)
(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

45. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

46. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

47. Labor Code § 223 provides, "Where any statute or contract requires an employer to maintain the designated wage scale, it shall be unlawful to secretly pay a lower wage while purporting to pay the wage designated by statute or by contract."

48. Labor Code § 1197 states, "The minimum wage for employees fixed by the commission is the minimum wage to be paid to employees, and the payment of a less wage than minimum wage so fixed is unlawful."

49. Labor Code § 1198 states, "The maximum hours of work and the standard conditions of labor fixed by the commission shall be the maximum hours of work and the standard conditions of labor for employees. The employment of any employee for longer hours than those fixed by the order or under conditions of labor prohibited by the order is unlawful."

50. The "Minimum Wages" section and the "Hours and Days of Work" section of the applicable Wage Order provides as a standard of conditions of labor that employees be paid at least the applicable minimum wage and overtime wages for regular time and overtime time suffered or permitted to work respectively.

51. Labor Code § 1194 states "Notwithstanding any agreement to work for a lesser wage, any

employee receiving less than the legal minimum wage or the legal overtime compensation applicable to the employee is entitled to recover in a civil action the unpaid balance of the full amount of his minimum wage or overtime compensation, including interest thereon, reasonable attorney's fees and costs of suit."

52. At all relevant times hereto, DEFENDANTS were PLAINTIFF'S employer within the meaning of Labor Code who violated or caused to be violated the relevant sections of the Labor Code and other provisions regulating hours and days of work per the applicable Wage Order; as such, DEFENDANTS is subject to the payment of the underpaid wages and penalties to PLAINTIFF, who was affected by DEFENDANTS' violation of this section.

53. DEFENDANTS' uniform practices and/or treatment of PLAINTIFF required that PLAINTIFF frequently work regular and overtime hours without compensation. Throughout the time period relevant to this Complaint, and during PLAINTIFF'S employment period, PLAINTIFF often worked beyond eight (8) hours per day and/or (40) hours per week without legally-required compensation for all of that time, let alone at any overtime rate. Among other things that occurred: (a) one or more of DEFENDANTS' authorized agents instructed PLAINTIFF to perform work "off-the-clock" prior to, during and/or subsequent to his scheduled shift; (b) one or more of each of the DEFENDANTS' authorized agents required PLAINTIFF to perform essential job functions while he was punched-out for his meal, such that PLAINTIFF performed work "off-the-clock." In addition, DEFENDANTS routinely deprived PLAINTIFF of his rightful wages, including overtime pay. On information and belief, PLAINTIFF alleges that DEFENDANTS had the ability to monitor and did monitor the hours worked by PLAINTIFF; DEFENDANTS therefore, knew or should have known that the PLAINTIFF routinely worked substantial time without compensation, let alone at an overtime rate.

54. During the time period relevant to this Complaint, DEFENDANTS failed to pay PLAINTIFF for all hours worked and paid PLAINTIFF a lower wage than contractually promised and legally required. At all times relevant to this Complaint, DEFENDANTS directly and/or indirectly paid PLAINTIFF less than minimum wage for all times suffered or permitted to work for DEFENDANTS, particularly when evaluating PLAINTIFF'S hourly wage against his actual work hours and considering

hours worked "off-the-clock." DEFENDANTS failed to satisfy minimum wage requirements by secretly paying PLAINTIFF a lower wage while purporting to pay the wage designated by agreement/contract between the parties; this occurred, *inter alia,* when DEFENDANTS failed to pay PLAINTIFF for all hours worked, *i.e.* "off-the-clock" work that was incidental to PLAINTIFF'S daily duties and responsibilities and DEFENDANTS routinely deprived PLAINTIFF of his rightful wages.

55. By their conduct during the applicable statutory period, including but not limited to the conduct herein described (which includes but is not limited to matters alleged on information and belief), DEFENDANTS directly and/or indirectly underpaid wages to PLAINTIFF for all times suffered or permitted to work for DEFENDANTS, failed to pay overtime wages, failed to satisfy minimum wage requirements, failed to pay wages required by contract and/or law, and secretly paid a lower wage while purporting to pay the wage designated by agreement/contract between the parties in violation of Labor Code §§ 223, 1197, 1198 and the applicable Wage Orders.

56. As a direct result of DEFENDANTS' violations alleged herein, PLAINTIFF has suffered and continues to suffer, substantial losses including but not limited to the use and enjoyment of such unpaid wages, lost interest on such monies and expenses and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform its obligation under state law, all to PLAINTIFF'S damage in amounts according to proof at trial and within the jurisdictional limitations of this Court.

57. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §§ 223, 510, 1194, 1194.2, 1197, 1198 and Code of Civil Procedure § 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

THIRD CAUSE OF ACTION

Failure to Pay Minimum Wage

(Violation of Labor Code § 1194.2)

(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

58. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

59. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

60. California *Labor Code* § 1194.2(a) provides:

> In any action under Section 98, 1193.6, 1194, or 1197.1 to recover wages because of the payment of a wage less than the minimum wage fixed by an order of the commission or by statute, an employee shall be entitled to recover liquidated damages in an amount equal to the wages unlawfully unpaid and interest thereon.

61. DEFENDANTS' uniform practices and/or treatment of PLAINTIFF required that PLAINTIFF frequently work regular and overtime hours without compensation. Throughout the time period relevant to this Complaint, and during PLAINTIFF'S employment period, PLAINTIFF often worked beyond eight (8) hours per day and/or (40) hours per week without legally-required compensation for all of that time, let alone at any overtime rate. Among other things that occurred: (a) one or more of DEFENDANTS' authorized agents instructed PLAINTIFF to perform work "off-the-clock" prior to, during and/or subsequent to his scheduled shift; (b) one or more of each of the DEFENDANTS' authorized agents required PLAINTIFF to perform essential job functions while he was punched-out for his meal, such that PLAINTIFF performed work "off-the-clock." In addition, DEFENDANTS routinely deprived PLAINTIFF of his rightful wages, including overtime pay. On information and belief, PLAINTIFF alleges that DEFENDANTS had the ability to monitor and did monitor the hours worked by PLAINTIFF; DEFENDANTS therefore, knew or should have known that the PLAINTIFF routinely worked substantial time without compensation, let alone at an overtime rate.

62. During the time period relevant to this Complaint, DEFENDANTS failed to pay

PLAINTIFF for all hours worked and paid PLAINTIFF a lower wage than contractually promised and legally required. At all times relevant to this Complaint, DEFENDANTS directly and/or indirectly paid PLAINTIFF less than minimum wage for all times suffered or permitted to work for DEFENDANTS, particularly when evaluating PLAINTIFF'S hourly wage against his actual work hours and considering hours worked "off-the-clock." DEFENDANTS failed to satisfy minimum wage requirements by secretly paying PLAINTIFF a lower wage while purporting to pay the wage designated by agreement/contract between the parties; this occurred, *inter alia,* when DEFENDANTS failed to pay PLAINTIFF for all hours worked, *i.e.* "off-the-clock" work that was incidental to PLAINTIFF'S daily duties and responsibilities and DEFENDANTS routinely deprived PLAINTIFF of his rightful wages.

63. By its conduct during the applicable statutory period, including but not limited to the conduct herein described (which includes but is not limited to matters alleged on information and belief), DEFENDANTS directly and/or indirectly underpaid wages to PLAINTIFF for all times suffered or permitted to work for DEFENDANTS, failed to pay overtime wages, failed to satisfy minimum wage requirements, failed to pay wages required by contract and/or law, and secretly paid a lower wage while purporting to pay the wage designated by agreement/contract between the parties in violation of Labor Code §§ 223, 1197, 1198 and the applicable Wage Orders.

64. As a result, DEFENDANTS failed to pay PLAINTIFF at least the required minimum wage for all hours worked and overtime. DEFENDANTS' conduct violates California law.

65. DEFENDANTS have intentionally, improperly and in bad faith failed to make payment of minimum wages, overtime compensation and other benefits to PLAINTIFF in violation of the Labor Code, applicable regulations, and the IWC Wage Orders.

66. As a result of DEFENDANTS' failure to pay to PLAINTIFF the minimum wages for all hours worked, DEFENDANTS owe to PLAINTIFF all unpaid minimum wages due, plus liquidated damages in an amount equal to the minimum wages owed, plus interest thereon, pursuant to Labor Code § 1194.2, in amounts according to proof at trial and within the jurisdictional limitations of this Court.

67. Accordingly, PLAINTIFF is entitled to all unpaid minimum wages due, plus a liquidated

damage equal to the amount of the minimum wage unpaid, plus interest thereon, pursuant to *Labor Code § 1194.2*, all to PLAINTIFF'S damages in the amounts according to proof at trial and within the jurisdictional limitations of this Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

FOURTH CAUSE OF ACTION

Failure to Indemnify for Expenses and Losses in Discharging Duties
(Violation of Labor Code §§ 2802)
(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

68. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

69. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

70. Labor Code § 2802(a) provides that "[a]n employer shall indemnify his or her employee for all necessary expenditures or losses incurred by the employee in direct consequence of the discharge of his or her duties, or of his or her obedience to the directions of the employer, even though unlawful, unless the employee, at the time of obeying the directions, believed them to be unlawful."

71. California Code of Regulations Title 8, § 111400, paragraph 9, subdivision (A), further states that "When uniforms are required by the employer to be worn by the employee as a condition of employment, such uniforms shall be provided and maintained by the employer." DEFENDANTS have violated this regulation by failing to provide and maintain the employees' uniforms.

72. Pursuant to Labor Code § 2804 any contract or agreement, express or implied, made by any employee to waive the benefits of Section 2802 or any part thereof, is null and void.

73. At all times relevant to the Complaint, DEFENDANTS required PLAINTIFF to bear necessary job expenses and failed to indemnify or reimburse PLAINTIFF for such expenses. This includes but is not limited to: (a) the cost of cell phone service which was required of PLAINTIFF to perform his daily job duties.

74. Through DEFENDANTS' conduct during the applicable statutory period including, but

not limited to, the conduct set forth herein, including that alleged on information and belief, DEFENDANTS required PLAINTIFF to pay for certain expenses and employment-related costs that are the responsibility of DEFENDANTS to pay and failed to indemnify PLAINTIFF as required by Labor Code § 2802.

75. Any agreement or contract made by PLAINTIFF to waive the benefits of Labor Code § 2802 is null and void.

76. Labor Code § 2802(c) states that "[f]or purpose of [2802], the term 'necessary expenditures or losses shall include all reasonable costs, including, but not limited to attorney's fees incurred by the employee enforcing the rights granted by [2802]."

77. As a direct result of DEFENDANTS' violations alleged herein, PLAINTIFF has suffered and continues to suffer, substantial losses related to the failure to be indemnified for necessary job expenses and losses, including the use and enjoyment of such monies, lost interest on such monies and expenses and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform on its obligations under state law, all to his damage in amounts according to proof at trial and within the jurisdictional limitations of this Court.

78. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to unpaid balance of the indemnification from DEFENDANTS' violations, interest thereon permitted by Labor Code § 2802(b), recovery of penalties, reasonable attorney's fees and costs of suit, injunctive relief, and any other permitted remedies including those permitted pursuant to the Labor Code §§ 2802, 2804 and Code of Civil Procedure § 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

FIFTH CAUSE OF ACTION

Failure to Provide Meal Periods

(Violation of Labor Code §§ 226.7, 512, and IWC Wage Order "Meal Periods" Section)

(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

79. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

80. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

81. Labor Code § 512 provides "[a]n employer may not employ an employee for a work period of more than five hours per day without providing the employee with a meal period of not less than 30 minutes, except that if the total work period per day of the employee is no more than six hours, the meal period may be waived by mutual consent of both the employer and employee. An employer may not employ an employee for a work period of more than 10 hours per day without providing the employee with a second meal period of not less than 30 minutes, except that if the total hours worked is no more than 12 hours, the second meal period may be waived by mutual consent of the employer and the employee only if the first meal period was not waived."

82. The "Meal Period" section of the applicable Wage Order provides as a standard of condition of labor that an employee working more than five hours be provided a meal period of not less than 30 minutes, except when a work period of not more than six hours will complete the day's work and the meal period is waived by mutual consent of the employee and employer.

83. Labor Code § 226.7 provides "[a]n employer shall not require an employee to work during a meal or rest or recovery period mandated pursuant to an applicable statute, or applicable regulation, standard, or order of the Industrial Welfare Commission, the Occupational Safety and Health Standards Board, or the Division of Occupational Safety and Health."

84. Pursuant to Labor Code § 226.7(c) and "Meal Period" section of the applicable Wage Order, if an employer fails to provide an employee a meal period in accordance with a state law, the employer shall pay the employee one hour of pay at the employee's regular rate of compensation for each workday that the meal period is not provided.

85. Through DEFENDANTS' conduct during the applicable statutory period including, but not limited to, the conduct set forth herein, including that alleged on information and belief,

DEFENDANTS lacked a policy which directly and/or indirectly relieved PLAINTIFF'S of all duty for timely uninterrupted 30-minute periods at all times suffered or permitted to work for DEFENDANTS, and, in fact, had practices and procedures that impeded PLAINTIFF from taking such meal breaks. At all times relevant hereto, PLAINTIFF has not been allowed all timely meal breaks.

86. As a direct result of DEFENDANTS' violations alleged herein, PLAINTIFF has suffered and continues to suffer, substantial losses related to the failure to receive proper meal breaks, including the use and enjoyment of unpaid premiums wages from missed meal breaks, lost interest on such monies and expenses, and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform on its obligations under state law, all to PLAINTIFF'S damages in amounts according to proof at trial and within the jurisdictional limitations of this Court.

87. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §§ 226.7, 510, 512 and Code of Civil Procedure § 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

SIXTH CAUSE OF ACTION

Failure to Provide Rest Periods

(Violation of Labor Code § 226.7 and IWC Wage Order "Rest Periods" Section)

(Alleged by PLAINTIFF against DEFENDANTS, and all applicable DOES 1-30)

88. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

89. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

90. The "Rest Period" section of the applicable Wage Order provides as a standard of condition of labor employers must authorize and permit nonexempt employees to take a rest period at the

minimum rate of a net ten (10) consecutive minutes for each four (4) hour work period, or major fraction thereof.

91. Labor Code § 226.7 provides "[a]n employer shall not require an employee to work during a meal or rest or recovery period mandated pursuant to an applicable statute, or applicable regulation, standard, or order of the Industrial Welfare Commission, the Occupational Safety and Health Standards Board, or the Division of Occupational Safety and Health."

92. Through DEFENDANTS' conduct during the applicable statutory period including, but not limited to, the conduct set forth herein, including that alleged on information and belief, DEFENDANTS lacked a policy which directly and/or indirectly authorized and permitted PLAINTIFF to take rest periods at all times suffered or permitted to work for DEFENDANTS, and, in fact, had practices and procedures that impeded PLAINTIFF from taking such rest breaks. At all times relevant hereto, PLAINTIFF was not allowed all rest breaks.

93. Pursuant to Labor Code § 226.7(c) and "Rest Period" section of the applicable Wage Order, if an employer fails to provide an employee a rest period in accordance with a state law, the employer shall pay the employee one hour of pay at the employee's regular rate of compensation for each workday that the rest period that the employer failed to authorize or permit.

94. As a direct result of DEFENDANTS' violations alleged herein, PLAINTIFF has suffered and continues to suffer, substantial losses related to the failure to receive proper rest breaks, including the use and enjoyment of unpaid premiums wages from missed rest breaks, lost interest on such monies and expenses, and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform on its obligations under state law, all to their PLAINTIFF'S damages in amounts according to proof at trial and within the jurisdictional limitations of this Court.

95. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §§ 226.7, 510, 512 and Code of Civil Procedure §

1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

SEVENTH CAUSE OF ACTION

Failure to Provide and Maintain Accurate Itemized Wage Statements
(Violation of Labor Code §§ 226, 1174, 1198 and
IWC Wage Order "Records" Section)
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

96. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

97. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

98. Labor Code § 226(a) states in pertinent part "Every employer shall, semimonthly or at the time of each payment of wages, furnish each of his or her employees, either as a detachable part of the check, draft, or voucher paying the employee's wages, or separately when wages are paid by personal check or cash, an accurate itemized statement in writing showing":

i. Gross wages earned;

ii. Total hours worked by the employee, except for any employee whose compensation is solely based on a salary and who is exempt from payment of overtime under subdivision (a) of Section 515 or any applicable order of the Industrial Welfare Commission;

iii. the number of piece-rate units earned and any applicable piece rate if the employee is paid on a piece-rate basis;

iv. All deductions;

v. Net wages earned;

vi. The inclusive dates of the period for which the employee is paid;

vii. The name of the employee and only the last four digits of his or her social security number or an employee identification number other than a social security number;

viii. The name and address of the legal entity that is the employer;

ix. All applicable hourly rates in effect during the pay period and the corresponding number of hours worked at each hourly rate by the employee. The deductions made from payment of wages shall be recorded in ink or other indelible form, properly dated, showing the month, day, and year, and a copy of the statement and the record of the deductions shall be kept on file by the employer for at least three years at the place of employment or at a central location within the State of California.

99. Labor Code § 1174 requires employers to maintain records containing the information specified in § 1174 including but not limited to employees' total hours worked, an accurate hourly rate, accurate computation of net wages and when employees begin and end each work period.

100. Labor Code § 1198 states: "The maximum hours of work and the standard conditions of labor fixed by the commission shall be the maximum hours of work and the standard conditions of labor for employees. The employment of any employee for longer hours than those fixed by the order or under conditions of labor prohibited by the order is unlawful."

101. The "Records" section of the applicable Wage Order provides as a standard of condition of labor that accurate records be maintained by the employer including but not limited to the total hours worked in the payroll period and applicable rates of pay.

102. Labor Code § 226(e)(1) states "An employee suffering injury as a result of a knowing and intentional failure by an employer to comply with subdivision (a) is entitled to recover the greater of all actual damages or fifty dollars ($50) for the initial pay period in which a violation occurs and one hundred dollars ($100) per employee for each violation in a subsequent pay period, not to exceed an aggregate penalty of four thousand dollars ($4,000), and is entitled to an award of costs and reasonable attorney's fees."

103. Labor Code § 226(e)(2)(A) provides that an employee is deemed to suffer injury for purposes of Section 226(e) of the Labor Code if the employer fails to provide a wage statement. Furthermore, pursuant to Labor Code § 226(e)(2)(B), an employee is deemed to suffer injury for purposes

of Section 226(e) of the Labor Code if the employer fails to provide accurate and complete information as required by any one or more items (1) to (9), inclusive, of subdivision (a) and the employee cannot promptly and easily determine from the wage statement alone one or more of the items specified in Labor Code § 226(e)(2)(B)(i)-(iv).

104. Labor Code § 226(h) states "An employee may also bring an action for injunctive relief to ensure compliance with this section and is entitled to an award of costs and reasonable attorney's fees."

105. Through DEFENDANTS' conduct during the applicable statutory period including, but not limited to, the conduct set forth herein, including that alleged on information and belief, DEFENDANTS violated Labor Code §§ 226(a), 1174 and 1198 and the applicable Wage Order by knowingly and intentionally failing to maintain records and provide accurate itemized wage statements to PLAINTIFF reflecting, amongst other things, accurate figures for total hours worked, gross wages earned, and the hourly rate.

106. PLAINTIFF suffered injuries as a result of DEFENDANTS' intentional and knowing failure to provide and maintain accurate writings required by Labor Code §§ 226(a) and 1175, as herein alleged. DEFENDANTS' failure to provide and maintain accurate statements, as herein alleged, impeded PLAINTIFF from fully knowing, understanding, and being to inquire as to the hours worked and wages earned and due.

107. As a direct result of DEFENDANTS' violations alleged herein, PLAINTIFF has suffered and continues to suffer, substantial losses related to the failure to receive proper wage statements, including expenses and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform on its obligations under state law, all to PLAINTIFF'S damages in amounts according to proof at trial and within the jurisdictional limitations of this Court.

108. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, injunctive relief, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §§226 et seq., 1174, 1197, 1198 and Code

of Civil Procedure § 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

EIGHTH CAUSE OF ACTION

Failure to Pay Wages Due Upon Termination
(Violation of Labor Code §§ 201, 202, 203 and IWC Wage Order)
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

109. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

110. At all relevant times hereto, PLAINTIFF was a non-exempt employee of DEFENDANTS under the laws of the State of California within the meaning of the Labor Code and Wage Order.

111. Labor Code § 201(a) states "If an employer discharges an employee, the wages earned and unpaid at the time of discharge are due and payable immediately."

112. Labor Code § 202(a) states "If an employee not having a written contract for a definite period quits his or her employment, his or her wages shall become due and payable not later than 72 hours thereafter, unless the employee has given 72 hours' previous notice of his or her intention to quit, in which case the employee is entitled to his or her wages at the time of quitting. Notwithstanding any other provision of law, an employee who quits without providing a 72-hour notice shall be entitled to receive payment by mail if he or she so requests and designates a mailing address. The date of the mailing shall constitute the date of payment for purposes of the requirement to provide payment within 72 hours of the notice of quitting."

113. During time relevant herein, flowing from their failures with respect to the compensation and indemnification of PLAINTIFF, as alleged above, DEFENDANTS regularly failed to timely issue complete and accurate wage statements to PLAINTIFF. Likewise, DEFENDANTS failed to timely remit final payments in full to PLAINTIFF, who no longer works for DEFENDANTS.

114. PLAINTIFF'S employment ended with DEFENDANTS on or about February 24, 2021.

115. Through DEFENDANTS' conduct during the applicable statutory period, including but

not limited to the conduct herein described (which includes but is not limited to matters alleged on information and belief), DEFENDANTS willfully failed to provide PLAINTIFF with all wages due and owing – including but not limited to wages for "off-the-clock" hours, sub-minimum wage payments, and unpaid overtime – within the time requirements set forth in Sections 201(a) and 202(a) of Labor Code.

116. Labor Code § 203(a) states, in relevant part, "If an employer willfully fails to pay, without abatement or reduction, in accordance with sections 201, 201.3, 201.5, 202, and 205.5, any wages of an employee who is discharged or who quits, the wages of the employee shall continue as a penalty from the due date thereof at the same rate until paid or until an action therefor is commenced; but the wages shall not continue for more than 30 days."

117. As a direct result of DEFENDANTS' violations as hereinabove set forth, PLAINTIFF has suffered and continues to suffer, substantial losses related to the use and enjoyment of such wages, as the result of DEFENDANTS' failure to maintain records in compliance with the Labor Code and Wage Order including but not limited to the expenses and attorney's fees and costs in seeking to compel DEFENDANTS to fully perform its obligation under state law, all to their respective damage in amounts according to proof at trial and within the jurisdictional limitations of this Court.

118. PLAINTIFF seeks to recover in a civil action to the fullest extent permissible all available remedies including but not limited to all monies that DEFENDANTS should have lawfully paid, penalties, injunctive relief, interest, reasonable attorney's fees and costs of suit, and any other permitted remedies including those permitted pursuant to the Labor Code §203 and Code of Civil Procedure § 1021.5. The exact amount of the applicable penalties is an amount to be shown according to proof at trial and within the jurisdictional limits of the Court.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

NINTH CAUSE OF ACTION

Unfair Business Practices

(Business & Professions Code §§ 17200, et seq.)

(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

119. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each

and every paragraph above, as though fully set forth herein.

120. Business & Professions Code § 17200 states: "As used in this chapter, unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter 1 (commencing with Section 17500) of Part 3 of Division 7 of the Business and Professions Code."

121. PLAINTIFF alleges on information and belief that DEFENDANTS' acts and omissions, as described in this Complaint, violate the Civil Code, Labor Code and the applicable Wage Order. PLAINTIFF alleges on information and belief that DEFENDANTS knew or should have known of the unlawful nature of their respective acts and omissions, as described in this Complaint – and that such conduct reflects a deliberate scheme to lower payroll costs and gain an unfair workforce advantage, contrary to public policy.

122. PLAINTIFF further alleges on information and belief that such acts and omissions constitute unlawful business practices and amount to policies in violation of FEHA given that they occurred in a continuing and systematic manner over a substantial period of time to the detriment of PLAINTIFF and other employees. Examples of such unlawful acts and omissions that occurred within four (4) years prior of the filing of this Complaint include, without limitation, DEFENDANTS' failure to (i) pay proper wages, including that of overtime wages, "all hours worked," "off-the-clock" hours, and payment of wages at the rate designated by statute or by contract; (ii) indemnify and reimburse expenses incurred in discharging duties; (iii) provide all required code-compliant meal and rest breaks; (iv) pay timely wages upon termination of employment; (v) maintain accurate records and provide and maintain accurate itemized wage statements; (vi) prevent harassment, discrimination and retaliation against persons who engage in protected activities; (vii) prevent harassment, discrimination and retaliation against persons who are members of a protected class; (viii) offer reasonable accommodations of restrictions in light of employee work restrictions; and (ix) prevent discrimination and retaliation against persons who present a medical condition or disability which requires accommodation.

123. PLAINTIFF is informed and believes, and on that basis alleges that, at all times herein

mentioned, DEFENDANTS, by and through its respective agents, including but not limited to DARIO, MANPREET, and JUANITA, engaged in the above-mentioned acts of unlawful, deceptive, and unfair business practices prohibited by Business and Professions Code §§ 17200 et seq., including those set forth in this paragraph, and thereby deprived PLAINTIFF and others of minimum working standards and conditions due, including those under Labor Code and Wage Order.

124. By their conduct during the applicable statutory period, including but not limited to the conduct herein described (which includes but is not limited to matters alleged on information and belief), DEFENDANTS engaged in unfair business practices in violation of Business & Professions Code § 17200, *et seq.*, and the applicable Industrial Welfare Commission Wage Orders. DEFENDANTS' use of such practices constitutes unfair competition and provides as unfair advantage over DEFENDANTS' competitors who conduct business in the State of California and comply with their obligations to: follow minimum wage laws; properly pay all wages and compensation earned (including any overtime); provide timely, off-duty meal and rest breaks; indemnify necessary job expenses; offer reasonable accommodations; refrain from retaliation; treat employees presenting a physical disability fairly; refrain from discrimination against employees presenting work restrictions; and generally maintain a safe and reasonable work environment.

125. As a result of DEFENDANTS' unfair competition and unlawful business practices, as herein alleged, PLAINTIFF suffered injury in fact and lost money or property; specifically, DEFENDANTS' unfair business practices directly deprived PLAINTIFF of his rightful wages and benefits. Pursuant to Business & Professions Code § 17203, PLAINTIFF is entitled to seek restitution of all wages and other monies owed belonging to PLAINTIFF, including interest thereon, which DEFENDANTS wrongfully withheld and retained for itself by means of its unlawful and unfair business practices.

126. PLAINTIFF is entitled to an injunction and other declaratory and equitable relief against such practices to prevent future damage for which there is no adequate remedy at law, and to avoid a multiplicity of lawsuits.

127. PLAINTIFF is informed and believes, and on that basis alleges, that the illegal conduct herein alleged is continuing, and that there is no indication that DEFENDANTS will cease and desist from such activity into the future. PLAINTIFF further alleges that if DEFENDANTS is not enjoined from the conduct set forth in this Complaint, DEFENDANTS will continue to fail to pay require wages/compensation and will continue to the other Labor Code and Wage Order requirements specified in this Complaint.

128. As a direct and proximate result of DEFENDANTS' conduct, DEFENDANTS has received and will continue to receive monies that rightfully belong to members of the general public who have been adversely affected by DEFENDANTS' conduct, as well as to PLAINTIFF by virtue of unpaid wages, out-of-pocket job expenses, unpaid premium wages and other monies.

129. PLAINTIFF is entitled and seeks any and all available remedies including but not limited to restitution and recovery of reasonable attorney's fees and costs pursuant to Code of Civil Procedure § 1021.5, Business and Professions Code § 17200 et seq., the substantial benefit doctrine, and/or the common fund doctrine.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

TENTH CAUSE OF ACTION

Retaliation

(Violation of Cal. Labor Code §232.5)

(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

130. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

131. At all relevant times herein, California Labor Code §232.5 was in effect and applied to DEFENDANTS. Section 232.5 (c) prohibits employers from requiring "as a condition of employment, that an employee refrain from disclosing information about the employer's working conditions..." or from discharging, formally disciplining or otherwise discriminating against employees who disclose information about the employer's working conditions.

132. At all times relevant herein, DEFENDANTS was PLAINTIFF'S employers in that

DEFENDANTS exercised control over the wages, hours, and working conditions of PLAINTIFF.

133. Throughout the time period relevant to this Complaint, PLAINTIFF observed, reported, and attempted to prevent the unsafe work conditions and unlawful conduct committed by, at the direction of and/ or under the control and supervision of DEFENDANTS. This includes, without limitation: (a) complaining about a lack of proper rest and/or meals breaks; (b) complaining about unpaid hours including overtime; (c) complaining of being unable to use sick leave days; and (d) asserting the right to receive medical care and reasonable accommodations in conjunction with disability/medical conditions resulting from a workplace injury. Examples of such harassment, discrimination, and retaliation include, without limitation:

a) Refusing to provide PLAINTIFF with medical care for his workplace injuries;

b) Refusing to engage in an interactive dialogue with PLAINTIFF to determine what reasonable accommodations he required as a result of his workplace injuries;

c) Failing to provide PLAINTIFF with opportunities for legally-compliant meal and rest breaks;

d) Demanding that PLAINTIFF perform work off-clock;

e) Retaliating against PLAINTIFF by terminating his employment; and

f) Refusing to allow Plaintiff to use his sick leave days.

134. PLAINTIFF was terminated by DEFENDANTS at least in part in retaliation for PLAINTIFF'S disclosures regarding the working conditions as detailed herein.

135. As a direct and foreseeable result of the aforesaid acts of DEFENDANTS, PLAINTIFF has lost and will continue to lose income and benefits in an amount to be proven at the time of trial. PLAINTIFF claims such amount as damages together with pre-judgment interest pursuant to Civil Code §3287 and /or any other provision of law providing for pre-judgment interest.

136. As a result of the aforesaid acts of DEFENDANTS, PLAINTIFF claims general damages for mental and emotional distress and aggravation in an amount to be proven at the time of trial.

137. The above-described acts and omission of DEFENDANTS, by and through its managers/supervisors, including without limitation DARIO, MANPREET, and JUANITA were

perpetrated in deliberate, cold, callous, fraudulent and intentional manner in order to injure and damage PLAINTIFF and/or with a conscious disregard of PLAINTIFF'S rights. Such acts are despicable, and constitute malice, fraud and/or oppression within the meaning of Civil Code section 3294. PLAINTIFF requests an assessment of punitive damages against DEFENDANTS, in an amount to be proven at time of trial.

138. As a proximate result of the foregoing conduct, which violated the provisions of Labor Code section 232.5, PLAINTIFF has been forced to and will incur attorney's fees and costs in the prosecution of this claim, in an amount to be proven at trial for a proven violation of Labor Code §232.5.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

ELEVENTH CAUSE OF ACTION
(Wrongful Termination in Violation of Public Policy)
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

139. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

140. The public policy of the State of California, as codified, expressed and mandated in *Labor Code§* 1102.5 and other applicable law is to prohibit employers from: (1) implementing policies preventing employees from disclosing reasonably based suspicions of violations of state or federal statutes; (2) retaliating against employees who have disclosed, or the employer believes the employee disclosed or may disclosed reasonably based suspicions of violations of state or federal statutes to government agencies, to a person with authority over the employee, or to another employee who has authority to investigate, discover, or correct the violation or noncompliance; and (3) retaliating against employees who refuse to participate in activities that would result in violations of state or federal statutes. Additionally, it is the policy of the State of California as expressed in the Labor Code and its enabling regulations that non-exempt employees, such as PLAINTIFF herein, cannot be required to work in excess of forty hours during a week or in excess of eight hours per day without any remuneration for all hours worked and at the designated rate, including overtime pay as mandated by California labor code sections. Employees such as PLAINTIFF are also entitled to meal and rest periods, within the required time period,

reimbursement of expenses they incurred, and all other rights and benefits under Labor Codes and applicable Wage Order. Finally, employees cannot be terminated and/or harassed for complaining about an employer's refusal to comply with the provisions of Labor Code sections and other applicable labor laws. The public policy of the State of California prohibits employers from retaliating against their employees and discriminating against them for, *inter alia*: complaining about a discriminatory policy and/or practice; reporting and/or opposing a violation of statute and/or law making inquiries regarding payroll records; seeking the payment of unpaid, earned wages; reporting workplace injuries and seeking medical coverage for the treatment of such workplace injuries as permitted by workers compensation law. As a matter of public policy, California law recognizes the need to protect and safeguard the right and opportunity of all persons to seek and hold employment free from discrimination, harassment, and retaliation. These public policies of the State of California are designed to protect all employees and to promote the welfare and well-being of the community at large.

141. Additionally, the California Fair Employment and Housing Act (the "FEHA") [Gov. Code § 12900, *et seq.*] prohibits discrimination and harassment against an employee based the person's protected characteristic such as age and disability/ medical condition. As a matter of public policy, the FEHA recognizes the need to protect and safeguard the right and opportunity of all persons to seek and hold employment free from discrimination, harassment, and retaliation. [Gov. Code § 12920.] The California state legislature has directed that the FEHA be construed liberally so as to accomplish its purposes. [Gov, Code § 12993.] Moreover, the California Supreme Court has specifically held that one's right to be free from discrimination and harassment in the workplace is "fundamental." (*See, e.g., Brown v. Superior Court* (1984) 37 Cal.3d 477, 485.)

142. At all material times herein, up through the date of PLAINTIFF'S final day of work, DEFENDANTS' managing and supervisory employees, including but not limited to DARIO, MANPREET, and JUANITA, was acting within the course and scope of her/his employment with DEFENDANTS, was required to observe the public policy of this state, including those laws which prohibit discrimination based upon disability, and engagement in protected activities (*e.g.*, California

Government Code §§12940(a), 12940(h), 12941(a), and 12942) and violated those laws by undertaking the conduct and violations previously described in this Complaint. PLAINTIFF is further informed and believes that DEFENDANTS and its agents adhere to a secret policy to exit an employee prior to the time the employee actually wishes to leave employment if said employees are injured, and/or engaging in protected activities – as was the case with PLAINTIFF.

143. During the time period 2019-2021, PLAINTIFF was employed by DEFENDANTS to work. PLAINTIFF'S employment with DEFENDANTS ended on or about February 24, 2021, when DEFENDANTS fired his employment in retaliation for, among other things, seeking accommodations of his medical condition/disability caused by workplace injuries, as well as previous protected activities, set for the herein above.

144. PLAINTIFF is informed and believes, and on that basis alleges, that PLAINTIFF'S employment with DEFENDANTS ended in violation of fundamental public policies of the State of California, including, without limitation: (i) encouraging employees to make complaints/ raise concerns regarding DEFENDANTS' employment practice that the employees, such as PLAINTIFF herein, reasonably suspected to be unlawful and discriminatory conducts at workplace on the basis of disability/ medical condition, use/ request to use disability related-accommodation in violation of California's Fair Employment and Housing Act (FEHA) [Cal. Gov. Code § 12940(a)]; (ii) prohibiting employers from retaliating against employees for reporting a work-related injuries and making request for accommodation, medical coverage and medical treatments; (iii) prohibiting employers from discriminating and retaliating against employees for complaining and reporting information about employer's working conditions and/or making inquiries about payroll records and unpaid owed wages; (iv) encouraging employees who work in private businesses such as DEFENDANTS' business, herein, which in effect provides services to the public in general, to report suspected unsafe and dangerous conditions without fear of retaliation; (v) encouraging employees of private businesses such as DEFENDANTS' herein, which provide services to the public, to make complaints to their employers and/ or governmental agency regarding any suspected potential risk of exposure to injuries due to the

unsafe and dangerous conditions at work without fear of retaliation; (vi) encouraging employees to exercise their rights to refuse to engage in conducts and/or to perform work under conditions where employer's violation of health and safety law would create a real and apparent hazard to employees without fear of retaliation and discrimination; and (vii) encouraging the right to prohibit employers from discriminating and retaliating against employees, who make inquiries into their payroll records, hours request payment of their unpaid earned wages or benefits, and further disclose information about employer's unsafe working conditions. These fundamental public policies insure to the benefit of the public, and not just the private interests of the employer and employee. DEFENDANTS knew or should have known that such policies and practices clearly run afoul of public policy.

145. PLAINTIFF alleges that he was subject to discrimination and retaliation for refusing to engage in conducts that violated fundamental public policy, to wit, DEFENDANTS retaliated against PLAINTIFF and terminated his employment, in part, due to: (i) PLAINTIFF'S status in a protected classes (injury-related disability); (ii) PLAINTIFF seeking medical treating for his workplace injury; (iii) asserting his right to receive reasonable accommodations in conjunction with a disability resulting from a workplace injury ; (iv) speaking out against DEFENDANTS' unlawful policies and practices with respect to failure to reimburse job related expenses; (v) opposing DEFENDANTS' employment practices which require their employees, such as PLAINTIFFS, to work long hours, and overtime hours per day at a rate less than the rate designated by the Statute and/ or by contract as promised and without enumeration for all overtime [violation of Labor Code Section/ wage and hour law]; (vi) PLAINTIFF'S complaints about a lack of proper rest and/or meals breaks; and (vii) refusing to engage in conducts that violated fundamental public policy, to wit, a private business, herein, which is in effect provides goods and services to public to be healthy, safe and free from hazard as evidenced by, but not exclusive of, the regulations found in California Health and Safety Code, Cal/DOSHA.

146. PLAINTIFF opposed and reported the above unlawful practice and abusive misconduct to the DEFENDANTS through his supervisors/managers and brought their concerns to the DEFENDANTS about the situation, which angered the DEFENDANTS. PLAINTIFF asked the

DEFENDANTS to look into these matters and take corrective actions. DEFENDANTS ignored PLAINTIFF'S complaints and failed to take any corrective actions —and instead retaliated against him, as alleged hereinabove.

147. PLAINTIFF alleges, on information and belief, that he was targeted for termination and fired by DEFENDANTS – despite the fact that he had been a reliable and hardworking employee– due to his protected status (workplace injury-related disability) and engagement in multiple protected activities. Throughout his employment, PLAINTIFF performed the duties of his work assignments in a competent and proficient manner; he was at all times ready, willing and able to perform his tasks reliably and capably.

148. The actions and continuing course of the aforesaid conduct amounted to a systematic policy of discrimination and harassment, thereby constituting a continuing violation actionable under, among other things, Fair Employment Housing Act (FEHA) which reflects a fundamental public policy against discrimination in employment on account of age, disability/ medical condition and protected traits.

149. Instead of investigating PLAINTIFF'S respective reports of illegal/unlawful employment policies and practices and retaliatory/hostile work conditions, DEFENDANTS ratified illegal/unlawful employment policies and practices and retaliatory/hostile work conditions by retaliating against PLAINTIFF through, without limitation, refusing to engage in an interactive process, refusing to provide reasonable accommodations, and ultimately terminating PLAINTIFF.

150. In retaliating against and terminating PLAINTIFF for engaging in protected activities, DEFENDANTS violated the fundamental principles of the public policy of the State of California as reflected in its laws, objectives and policies, alleged above. Said laws, which establish these fundamental public policies include, without limitation: Cal. wage and hour law and laws and regulations pertaining to the public's safety, Cal. Labor Code §§ 232.5, 1102.5, 6410; Gov. Code § 12920; Gov. Code §12653; Gov. Code §12940 et seq.; Gov. Code § 12900, *et seq.*, the California Constitution; California Fair Employment and Housing Act (the "FEHA"), California Family Rights Act ("CFRA") Division 4 of

California Labor Code, worker's compensation and insurance, the Industrial Wage Commission promulgated by Division of Labor Standard Enforcement.

151. PLAINTIFF'S report of/opposition to/complaint about the work condition and DEFENDANTS' unlawful employment practices and policies at its businesses, including discrimination, unhealthy and unsafe work conditions, as alleged herein above, was a substantial motivating reason for PLAINTIFF being discriminated/ retaliated against and ultimately discharged.

152. On information and belief, DEFENDANTS knowingly subjected its employees/staff and the customers to whom it provided services to actual and potential harm deliberately terminating whistleblowers who reported unlawful and/or unsafe working conditions in order to avoid negative publicity and economic harm.

153. By the aforesaid acts and conduct, PLAINTIFF has been directly and legally caused to suffer actual damages pursuant to California *Civil Code* § 3333 including, but not limited to, loss of earnings and future earning capacity, medical and related expenses for care and procedures both now and in the future, attorney's fees, and other pecuniary loss not presently ascertained, for which PLAINTIFF will seek leave of court to amend when ascertained.

154. DEFENDANTS' conduct was a substantial factor in causing PLAINTIFF'S harm.

155. As a direct, foreseeable, and proximate result of each DEFENDANTS' conduct, PLAINTIFF is caused to suffer and continues to suffer substantial losses in earnings, employment benefits, employment opportunities, and PLAINTIFF has suffered from humiliation, anxiety, severe emotional distress, worry, fear, and special damages (to include lost wages) all to his special and general damage in an amount to be determined at time of trial and in excess of the jurisdictional minimum of this court.

156. PLAINTIFF is informed and believes that DEFENDANTS and its respective agents undertook the alleged retaliation intentionally, oppressively, and maliciously, with an evil and malevolent motive to injure PLAINTIFF and a willful and conscious disregard for PLAINTIFF'S rights, health, and safety. Each decision to terminate PLAINTIFF ran afoul of public policy; such termination can be

accurately characterized as oppression, malice, and fraud – and ought not to be suffered by any member of the community. Moreover, the wrongful termination herein described was perpetrated by employees whom DEFENDANTS knew or should have known to be unfit and/or possessive of a conscious disregard or the rights of others. In this connection, PLAINTIFF alleges advance knowledge, conscious disregard, authorization, ratification, fraud and malice on the part of an officer, director or managing agent of DEFENDANTS – all entitling PLAINTIFF to recover exemplary and punitive damages in an amount to be determined at the time of trial.

157. PLAINTIFF is entitled to and seeks any and all available remedies including but not limited to economic damages (including back pay and front pay and all benefits), general damages (including pain and suffering), exemplary and punitive damages, and recovery of reasonable attorney's fees and costs pursuant to California Code of Civil Procedure § 1021.5, California Business and Professions Code § 17200 *et seq.*, the substantial benefit doctrine, and/or the common fund doctrine.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

TWELFTH CAUSE OF ACTION

Wrongful Termination [FEHA]
(Violation of Gov. Code §§12900 and 12940 et seq.)
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

158. PLAINTIFFS re-allege and incorporate herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

159. At all times mentioned in this Complaint, FEHA and California Government Codes §§ 12900 et seq. and 12940 et seq., were in full force and effect and binding on each of the DEFENDANTS. These sections require DEFENDANTS to refrain from harassing, discriminating or retaliating against any employee on the basis of race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, marital status, sex, age, or sexual orientation. The statements and conduct on the part of the DEFENDANTS complained of herein represent a violation of the FEHA and California Government Codes §§ 12900, et seq., and 12940, et seq., which states, in part:

> 12940. It is an unlawful employment practice... (a) For an employer, because of the race, religious creed, color, national origin, ancestry,

> physical disability, mental disability, medical condition, marital status, sex, age, or sexual orientation of any person, to refuse to hire or employ the person or to refuse to select the person for a training program leading to employment, or to bar or to discharge the person from employment or from a training program leading to employment, or to discriminate against the person in compensation or in terms, conditions, or privileges of employment.

160. During the time period 2019-2021, PLAINTIFF was employed by DEFENDANTS. PLAINTIFF'S employment with DEFENDANTS ended on or about February 24, 2021, when DEFENDANTS fired PLAINTIFF. PLAINTIFF alleges, on information and belief, that he was targeted for termination and fired by DEFENDANTS – despite the fact that he had been a reliable and hardworking employee– due to his protected status (workplace injury-related disability) and engagement in multiple protected activities. Throughout his employment, PLAINTIFF performed the duties of his work assignments in a competent and proficient manner; he was at all times ready, willing and able to perform his tasks reliably and capably.

161. At the time PLAINTIFF was subjected to DEFENDANTS' discrimination, retaliation and termination, PLAINTIFF was a member of several protected class under the California Government Code and the FEHA, as he suffered a medical condition/physical disability which required reasonable accommodation, as herein described.

162. DEFENDANTS are "covered employer" under the meaning of FEHA, as DEFENDANTS regularly employed five (5) or more persons during the relevant time period.

163. At the time of the discrimination and ultimate termination, PLAINTIFF was able to perform the essential job duties of his position following with a reasonable accommodation for his medical condition/disability.

164. Such reprehensible conduct by DEFENDANTS is in violation of the aforementioned Government Code sections and the FEHA.

165. As a proximate result of DEFENDANTS' conduct, PLAINTIFF has lost wages, benefits, other out of pocket losses and has suffered and continues to suffer humiliation, emotional distress, and mental and physical pain and anguish, all to his damages in a sum according to proof at time of trial.

166. As a further proximate result of DEFENDANTS' conduct and the consequences proximate caused by it, PLAINTIFF has suffered medical and related expenses in an amount according to proof at time of trial.

167. The acts and omissions of DEFENDANTS, as alleged in this Complaint, were willful, wanton, malicious, intentional, oppressive, despicable, and done in willful and conscious disregard of the rights, welfare and/or safety of PLAINTIFF. PLAINTIFF alleges that such acts and omissions were carried out by the respective managerial agents of DEFENDANTS and/or with the express knowledge, consent, and ratification of managerial employees of DEFENDANTS – thereby justifying the awarding of punitive and exemplary damages in an amount to be determined at the time of trial.

168. PLAINTIFF seeks to recover attorneys' fees given that FEHA provides that, "the court, in its discretion, may award to the prevailing party reasonable attorney's fees and costs, including expert witness fees. . .". Cal. Gov't Code § 12965(b).

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

THIRTEENTH CAUSE OF ACTION

Failure to Provide Reasonable Accommodation [FEHA]
(Violation of Cal. Gov. Code §§12940 (m), 12926(p); and Cal. Code Regs., Title 2 §11068)
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

169. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

170. PLAINTIFF is informed and believes, and thereupon allege, that Pursuant to California Government Code Sections 12926 (p) and 12940(m), California Code of Regulations, Title 2, Section 11068 promulgated by the Fair Employment Housing Act [FEHA], employers must make reasonable accommodations for employees with disabilities. Examples of reasonable accommodations include restructuring jobs, including reassigning or transferring an employee, developing part-time or modified work schedules, acquisition or modification of equipment or devices, and other similar accommodations for individuals with disabilities.

171. PLAINTIFF is informed and believes, and thereupon allege, that the Fair Employment

and Housing Act (FEHA) requires employers to reasonably accommodate the medical condition and physical disabilities of any employee if the work environment could have been modified or adjusted in manner that would have enabled employee to perform essential functions of job.

172. At all material times described herein, PLAINTIFF was an individual with disabilities within the meaning of Section 12926(i) & (k) of the Government Code. PLAINTIFF was able to perform the essential job duties for the position he held, with a reasonable accommodation.

173. At all material times herein, DEFENDANTS has continuously been an employer within the meaning of FEHA [Government Code § 12926(d)], regularly employing five or more employees.

174. At all material times herein, DEFENDANTS' respective managerial agents, including DARIO, MANPREET, and JUANITA, among others, were acting within the scope of their employment and within authority given to them by the DEFENDANTS as supervisors/managers of PLAINTIFF within the meaning of FEHA.

175. At all material times herein, DEFENDANTS failed to provide reasonable accommodation to PLAINTIFF's known disabilities in violation of Sections 12940(m) and 12926(p) of the Government Code and 2 C.C.R. §11068.

176. As a direct, foreseeable, and proximate result of DEFENDANTS' acts, as hereinabove alleged, PLAINTIFF suffered injuries and damages in an amount which will be proven at trial.

177. The acts and omissions of DEFENDANTS, as alleged in this Complaint, were willful, wanton, malicious, intentional, oppressive, despicable, and done in willful and conscious disregard of the rights, welfare and safety of PLAINTIFF. PLAINTIFF alleges that such acts and omissions were carried out by managerial agents of DEFENDANTS and/or with the express knowledge, consent, and ratification of managerial employees of DEFENDANTS – thereby justifying the awarding of punitive and exemplary damages in an amount to be determined at the time of trial.

178. Plaintiff seeks to recover attorneys' fees given that FEHA provides that, "the court, in its discretion, may award to the prevailing party reasonable attorney's fees and costs, including expert witness fees. . .". Cal. Gov't Code § 12965(b).

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

FOURTEENTH CAUSE OF ACTION

Failure to Engage in the Interactive Process [FEHA]
(Violation of Cal. Gov. Code §12940 (n))
(Alleged by PLAINTIFF against DEFENDANTS and all applicable DOES 1-30)

179. PLAINTIFF re-alleges and incorporates herein by this reference the allegations in each and every paragraph above, as though fully set forth herein.

180. At all material times herein, PLAINTIFF was employed by DEFENDANTS as a full-time employee, subject to the laws of the State of California, as set-forth in the Government Code, and was covered under one or more statutes and Regulations of the Fair Employment and Housing Act (FEHA).

181. At all times herein mentioned, FEHA, Cal. Gov't Code §§ 12900, et seq., was in full force and effect and was fully binding upon DEFENDANTS. Specifically, §12940(a) prohibits DEFENDANTS from harassing any of its employees, including PLAINTIFF on the basis of age, a medical condition, disability, invocation of a right to request/use disability-related accommodations, and reporting/opposition of discriminatory workplace conduct.

182. Cal. Gov. Code §12940 (n) provides the following, in pertinent part: "It shall be an unlawful employment practice ... (n) For an employer or other entity covered by this part to fail to engage in a timely, good faith, interactive process with the employee or applicant to determine effective reasonable accommodations, if any, in response to a request for reasonable accommodation by an employee or applicant with a known physical or mental disability or known medical condition."

183. At all material times herein, each of the DEFENDANTS has continuously been an employer within the meaning of FEHA [Government Code § 12926(d)], regularly employing five or more employees.

184. At all material times herein, DEFENDANTS' respective managerial agents, including DARIO, MANPREET, and JUANITA, among others, were acting within the scope of their employment and within authority given to them by the DEFENDANTS as supervisors/managers of PLAINTIFF within the meaning of FEHA.

185. PLAINTIFF is informed and believes, and on that basis alleges that at all times relevant hereto, DEFENDANTS (a) placed DARIO, MANPREET, and JUANITA, among others, in a position to supervise DEFENDANTS' day-to-day business operations and the work performances of their respective employees, including PLAINTIFF; and (b) empowered DARIO, MANPREET, and JUANITA, among others, to take tangible employment actions against PLAINTIFF to effect a significant change in PLAINTIFF'S employment status, including but not limited to actions substantially bearing on PLAINTIFF'S schedule and assignments, reported work hours, receipt of wages, record of disciplinary action, receipt of reasonable accommodations (or lack thereof), and employment status. In their respective roles as PLAINTIFF'S supervisor/manager, and as authorized agents for DEFENDANTS, DARIO, MANPREET, and JUANITA and others exercised unique authority over PLAINTIFF.

186. DEFENDANTS' conduct, as alleged herein, by and through their respective authorized agents, constitutes failure to engage in the interactive process, in violation of FEHA. As herein described, DEFENDANTS, by and through their respective authorized agents, failed to engage in a timely, good faith, interactive process with PLAINTIFF to determine effective reasonable accommodations, if any, in response to PLAINTIFF'S request for reasonable accommodation in connection with his known medical condition and related physical disability. In this connection, DEFENDANTS violated Government Code §12940 (n) as to PLAINTIFF.

187. DEFENDANTS' conducts, as alleged herein, by and through their authorized agents constitutes failure to engage in the interactive process, in violation of FEHA.

188. As a direct result of the unlawful employment practices of DEFENDANTS, as alleged above, PLAINTIFF has been deprived of a discrimination-free work environment, lost income and benefits, and suffered other damages to be determined at trial.

189. As a further and direct result of the unlawful employment practices of DEFENDANTS as alleged hereinabove, PLAINTIFF has suffered emotional distress, physical pain and suffering, and injuries in an amount to be proven at trial.

190. As a further result of DEFENDANTS' violations of FEHA, PLAINTIFF has been compelled to employ attorney's fees and are entitled to attorney's fees pursuant to Gov. Code §12965 and CCP §1021.5.

WHEREFORE, PLAINTIFF prays for judgment as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, PLAINTIFF prays for relief as follows:

a. For declaratory relief to the extent permitted by law;

b. For injunctive relief to the extent permitted by law including, but not limited to, as provided by the Labor Code § 226(h), and Business and Professions Code § 17200 et seq.;

c. For restitution as provided by Business and Professions Code § 17200 et seq.;

d. For an order requiring DEFENDANTS and all applicable DOES to restore and disgorge all funds to each affected person acquired by means of any act or practice declare by this Court to be unlawful, unfair or fraudulent and, therefore, constituting unfair competition under Business and Professions Code § 17200 et seq.;

e. For an award of unpaid wages, including overtime wages, wages for "all hours worked" to the extent permissible by law;

f. For an award of any and all monies required to be paid and/or reimbursed to Plaintiff including but not limited to monies required to be indemnified for;

g. For penalties to the extent permitted pursuant to the Labor Code and Wage Order including, but not limited to, waiting time penalties under Labor Code §§ 203, 223, 226 et seq., 226 (e), 226.7, 232.5, 510, 512, 1102.5; 1174, 1194, 1198, 2802, 6401;

h. For an award of damages to the extent permissible by the Labor Code and Civil Code, including Labor Code §§ 203, 223, 226 et seq., 226(e), 226.7, 232.5, 510, 512, 1102.5, 1174, 1194, 1198, 2802, 6401, and Civil Code §§1709, 1710, 3333;

i. For an award of liquidated damages to the extent permissible by Labor Code § 1194.2;

j. For an award of punitive damages to the extent permissible by law;

k. For a money judgment representing restitution damages together with interest on said amounts, according to proof;

l. For general and special damages according to proof;

m. For lost wages, loss of earning capacity, loss of benefits and/or other economic damages, according to proof;

n. For pre- and post-judgment interest to the extent permitted by law;

o. For reasonable attorneys' fees and cost of suit and, to the extent permitted by law, including pursuant to Cal. Labor Code §§ 218.5, 226 (e)(h), 1102.5, 1194 (a), and 2802(c), Code of Civil Procedure § 1021.5, and Cal. Gov't Code § 12965(b) [FEHA]

p. An award of such other and further relief as this Court deems proper and just.

DEMAND FOR JURY TRIAL

PLAINTIFF hereby demand trial of this matter by jury to the extent authorized by law.

Dated: July 26, 2021

LAW OFFICES OF PARVIZ DARABI

Parviz Darabi, Esq.
Attorney for Plaintiff

EXHIBIT "1"

STATE OF CALIFORNIA | Business, Consumer Services and Housing Agency GAVIN NEWSOM, GOVERNOR

DEPARTMENT OF FAIR EMPLOYMENT & HOUSING KEVIN KISH, DIRECTOR

2218 Kausen Drive, Suite 100 | Elk Grove | CA | 95758
(800) 884-1684 (Voice) | (800) 700-2320 (TTY) | California's Relay Service at 711
http://www.dfeh.ca.gov | Email: contact.center@dfeh.ca.gov

July 26, 2021

Parviz Darabi
500 AIRPORT BLVD., SUITE 410
BURLINGAME, California 94010

RE: **Notice to Complainant's Attorney**
DFEH Matter Number: 202107-14282726
Right to Sue: ORDONEZ / SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC. et al.

Dear Parviz Darabi:

Attached is a copy of your complaint of discrimination filed with the Department of Fair Employment and Housing (DFEH) pursuant to the California Fair Employment and Housing Act, Government Code section 12900 et seq. Also attached is a copy of your Notice of Case Closure and Right to Sue.

Pursuant to Government Code section 12962, DFEH will not serve these documents on the employer. You must serve the complaint separately, to all named respondents. Please refer to the attached Notice of Case Closure and Right to Sue for information regarding filing a private lawsuit in the State of California. A courtesy "Notice of Filing of Discrimination Complaint" is attached for your convenience.

Be advised that the DFEH does not review or edit the complaint form to ensure that it meets procedural or statutory requirements.

Sincerely,

Department of Fair Employment and Housing

STATE OF CALIFORNIA | Business, Consumer Services and Housing Agency GAVIN NEWSOM, GOVERNOR

DEPARTMENT OF FAIR EMPLOYMENT & HOUSING KEVIN KISH, DIRECTOR

2218 Kausen Drive, Suite 100 | Elk Grove | CA | 95758
(800) 884-1684 (Voice) | (800) 700-2320 (TTY) | California's Relay Service at 711
http://www.dfeh.ca.gov | Email: contact.center@dfeh.ca.gov

July 26, 2021

RE: **Notice of Filing of Discrimination Complaint**
DFEH Matter Number: 202107-14282726
Right to Sue: ORDONEZ / SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC. et al.

To All Respondent(s):

Enclosed is a copy of a complaint of discrimination that has been filed with the Department of Fair Employment and Housing (DFEH) in accordance with Government Code section 12960. This constitutes service of the complaint pursuant to Government Code section 12962. The complainant has requested an authorization to file a lawsuit. A copy of the Notice of Case Closure and Right to Sue is enclosed for your records.

This matter may qualify for DFEH's Small Employer Family Leave Mediation pilot program. Under this program, established under Government Code section 12945.21, a small employer with 5 -19 employees, charged with violation of the California Family Rights Act, Government Code section 12945.2, has the right to participate in DFEH's free voluntary mediation service. Under this program both the employee requesting an immediate right to sue and the employer charged with the violation may request that all parties participate in DFEH's free voluntary mediation service. A request for mediation must be made within 30 days of receipt of the Notice of Case Closure and Right to Sue. If mediation is requested, the employee is prohibited from filing a civil action until mediation is complete. The employee's statute of limitations to file a civil action, including for all related claims not arising under section 12945.2, is tolled from DFEH's receipt of a mediation request under section 12945.21 until mediation is complete. To request DFEH Small Employer Family Leave Mediation, email DRDOnlinerequests@dfeh.ca.gov and include the DFEH matter number indicated on the Right to Sue notice.

Please refer to the attached complaint for a list of all respondent(s) and their contact information.

No response to DFEH is requested or required.

Sincerely,

Department of Fair Employment and Housing

STATE OF CALIFORNIA | Business, Consumer Services and Housing Agency — GAVIN NEWSOM, GOVERNOR

DEPARTMENT OF FAIR EMPLOYMENT & HOUSING — KEVIN KISH, DIRECTOR

2218 Kausen Drive, Suite 100 | Elk Grove | CA | 95758
(800) 884-1684 (Voice) | (800) 700-2320 (TTY) | California's Relay Service at 711
http://www.dfeh.ca.gov | Email: contact.center@dfeh.ca.gov

July 26, 2021

DEBLIN MATEO GONZALEZ ORDONEZ
C/O THE LAW OFFICES OF PARVIZ DARABI, 500 AIRPORT BLVD., SUITE 410
BURLINGAME, California 94010

RE: **Notice of Case Closure and Right to Sue**
DFEH Matter Number: 202107-14282726
Right to Sue: ORDONEZ / SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC. et al.

Dear DEBLIN MATEO GONZALEZ ORDONEZ:

This letter informs you that the above-referenced complaint filed with the Department of Fair Employment and Housing (DFEH) has been closed effective July 26, 2021 because an immediate Right to Sue notice was requested.

This letter is also your Right to Sue notice. According to Government Code section 12965, subdivision (b), a civil action may be brought under the provisions of the Fair Employment and Housing Act against the person, employer, labor organization or employment agency named in the above-referenced complaint. The civil action must be filed within one year from the date of this letter.

This matter may qualify for DFEH's Small Employer Family Leave Mediation pilot program. Under this program, established under Government Code section 12945.21, a small employer with 5 -19 employees, charged with violation of the California Family Rights Act, Government Code section 12945.2, has the right to participate in DFEH's free voluntary mediation service. Under this program both the employee requesting an immediate right to sue and the employer charged with the violation may request that all parties participate in DFEH's free voluntary mediation service. A request for mediation must be submitted to the DFEH within 30 days of receipt of the Notice of Case Closure and Right to Sue. If mediation is requested, the employee is prohibited from filing a civil action until mediation is complete. The employee's statute of limitations to file a civil action, including for all related claims not arising under section 12945.2, is tolled from DFEH's receipt of a mediation request under section 12945.21 until mediation is complete. To request DFEH Small Employer Family Leave Mediation, email DRDOnlinerequests@dfeh.ca.gov and include the DFEH matter number indicated on the Right to Sue notice.

To obtain a federal Right to Sue notice, you must contact the U.S. Equal Employment Opportunity Commission (EEOC) to file a complaint within 30 days of receipt of this DFEH Notice of Case Closure or within 300 days of the alleged discriminatory act, whichever is earlier.

STATE OF CALIFORNIA | Business, Consumer Services and Housing Agency
GAVIN NEWSOM, GOVERNOR

DEPARTMENT OF FAIR EMPLOYMENT & HOUSING
KEVIN KISH, DIRECTOR

2218 Kausen Drive, Suite 100 | Elk Grove | CA | 95758
(800) 884-1684 (Voice) | (800) 700-2320 (TTY) | California's Relay Service at 711
http://www.dfeh.ca.gov | Email: contact.center@dfeh.ca.gov

Sincerely,

Department of Fair Employment and Housing

COMPLAINT OF EMPLOYMENT DISCRIMINATION
BEFORE THE STATE OF CALIFORNIA
DEPARTMENT OF FAIR EMPLOYMENT AND HOUSING
Under the California Fair Employment and Housing Act
(Gov. Code, § 12900 et seq.)

In the Matter of the Complaint of
DEBLIN MATEO GONZALEZ ORDONEZ DFEH No. 202107-14282726

Complainant,

vs.

SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC.
2336 Harrison Street
Oakland, California 94612

ALOM TECHNOLOGIES CORPORATION, a California Corporation
48105 WARM SPRINGS BLVD
FREMONT, California 95439-7498

Respondents

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1. Respondent **SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC.** is an **employer SILICON VALLEY TECHNICAL STAFFING, a California Corporation, also known as, SILICON VALLEY STAFFING GROUP, INC.** subject to suit under the California Fair Employment and Housing Act (FEHA) (Gov. Code, § 12900 et seq.).

2.Complainant is naming **ALOM TECHNOLOGIES CORPORATION, a California Corporation** business as Co-Respondent(s).

3. Complainant **DEBLIN MATEO GONZALEZ ORDONEZ**, resides in the City of **BURLINGAME,** State of **California.**

4. Complainant alleges that on or about **February 24, 2021**, respondent took the following adverse actions:

Complainant was harassed because of complainant's disability (physical or mental), medical condition (cancer or genetic characteristic).

Date Filed: July 26, 2021

Complainant was discriminated against because of complainant's disability (physical or mental), medical condition (cancer or genetic characteristic) and as a result of the discrimination was terminated, denied any employment benefit or privilege, denied reasonable accommodation for a disability.

Complainant experienced retaliation because complainant requested or used a disability-related accommodation and as a result was terminated, denied any employment benefit or privilege, denied reasonable accommodation for a disability.

Additional Complaint Details:

Date Filed: July 26, 2021

VERIFICATION

I, **PARVIZ DARABI**, am the **Attorney** in the above-entitled complaint. I have read the foregoing complaint and know the contents thereof. The matters alleged are based on information and belief, which I believe to be true.

On July 26, 2021, I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

BURLINGAME, CA

Date Filed: July 26, 2021

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

Hannah Kain

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/29/2023

Date

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

State of California, ss. County of Alameda

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

Original Signature

3/29/2023

Date

Subscribed and Sworn to before me this 29 day of MARCH.

Notary Public Signature

LYNETTE MARY LONG
Notary Public - California
Alameda County
Commission # 2431357
My Comm. Expires Jun 15, 2027

Applicant's initials HK

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: ALOM Technologies Corporation

Physical Address: 3910 Waldemere Ave.

City: Indianapolis State: IN Zip: 46241

Mailing Address (if different from physical address): 48105 Warm Springs Blvd.

City: Fremont State: CA Zip: 94539

Telephone: (510) 360-3641 Website: www.alom.com

Licensing Company Email: regulatory@alom.com

Section 2: Personal Information

First: Hannah Middle: Last: Kain

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

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

Mailing Address: [redacted]

City: San Jose State: CA Zip: 95126

Telephone: 510-360-3600 Email: hkain@alom.com

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

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

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

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

Applicant's initials HK

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

School Name		From - To (MM/YY – MM/YY)	
SCT Knuds Gymnasium		08/72-06/75	
Address	City	State	Zip
	Odense	Denmark	
Diploma/Degree obtained, if any			
Graduated High School			

School Name		From - To (MM/YY – MM/YY)	
Odense University		08/75-06/79	
Address	City	State	Zip
	Odense	Denmark	
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Aarhus University		06/79-01/83	
Address	City	State	Zip
	Aarhus	Denmark	
Diploma/Degree obtained, if any			
M.S.			

School Name		From - To (MM/YY – MM/YY)	
Syddansk University		07/83-07/86	
Address	City	State	Zip
	Kolding	Denmark	
Diploma/Degree obtained, if any			
B.S.			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/10-Present	[redacted]	San Jose	CA	95126
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials HK

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

Business Name			From - To (MM/YY – MM/YY)
ALOM			
Business Address	**City**	**State**	**Zip**
48021 Warm Springs Blvd.	Fremont	CA	94539
Phone	**Title**		
510-360-3600	CEO		
Description of Duties			
CEO			

Business Name			From - To (MM/YY – MM/YY)
Grimes Co. (Now Closed)			07/94-07/97
Business Address	**City**	**State**	**Zip**
1050 Ringwood Ave.	San Jose	CA	95131
Phone	**Title**		
NA	COO		
Description of Duties			
Run Division			

Business Name			From - To (MM/YY – MM/YY)
Citibag (Now Closed)			09/90-03/94
Business Address	**City**	**State**	**Zip**
1178 Frelinghuysen Ave.	Newark	NJ	07114
Phone	**Title**		
NA	Director of Marketing		
Description of Duties			
Marketing & Sales			

Business Name			From - To (MM/YY – MM/YY)
Baltica Finans (Now Closed)			07/86-06/90
Business Address	**City**	**State**	**Zip**
	Ballerup	Denmark	
Phone	**Title**		
NA	ASS. VP		
Description of Duties			
Marketing & Development			

Business Name			From - To (MM/YY – MM/YY)
ALFA-LAVAL			04/83-01/86
Business Address	**City**	**State**	**Zip**
	Kolding	Denmark	
Phone	**Title**		
	Global Marketing Manager		
Description of Duties			
Global Marketing			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
2020vet, Inc			01/14-02/16
Business Address	**City**	**State**	**Zip**
512 Pilarcitos Ave.	Half Moon Bay	CA	94019
Phone	**Title**		
	Director		
Description of Duties			
Board			

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

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

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

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

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

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

Applicant's initials HK

ALOM Technologies Corporation - List of Employees March 2023

Full name	Employee ID	Status
Aguirre Luna, Bibiana	[redacted]	Active
Ahmedi, Sameer		Active
Alcause, Liberty		Active
Aldana, Luciano R		Active
Alguera Rivas, Iris M		Active
Alguera Vasquez, Douglas E		Active
Anderson, Tyler		Active
Arenas, Migdia		Active
Arreguin, Andrea		Active
Arreola, Jessie M		Active
Arriaga, Alma		Active
Asahan, Randy		Active
Ayala, Fortino G		Active
Bautista Jr, Frank L		Active
Bautista, Richard		**LOA**
Bawihrin, Tlingnak		Active
Bernardino, Aldrin Gee V		Active
Biak, Pa		Active
Boddie, Candyce		Active
Brizuela, Ana L		Active
Brizuela, Mayra		Active
Brizuela, Nathalia		Active
Brown, Larry S		Active
Buan, Brenda		Active
Bubb, James D		Active
Bush, Shawn		Active
Cabrales, Shaira Ana S		Active
Calzada, Leticia A		Active
Cao, Nghiep		Active
Carr, Danielle R		Active
Cashion, Dawn M		Active
Castaneda, Dawn		Active
Castillo, Alex Jason P		Active
Castro, Jeanra		Active
Castro, Roda		Active
Cer, Mang		Active
Cerna, Rosana		Active
Chaudhary, Monika		Active
Chavez, Gloria		Active
Chen, YongJian		Active
Chicatto, Angel		Active
Chin, Thluai		Active
Chiu, Tony		Active
Choy, Simon		Active
Ciang, Sung		Active
Coles, Robert S		Active
Conley, Andrea		Active
Constanza, Yesenia M		Active
Contreras, Edgar		Active
Contreras, Roselia		Active
Dang, Thai Huyen Trinh		Active
Dao, Dung		Active
Dao, Le Thi Bich		Active
Dat D, Thi Thuy Diem T		Active
De La Cruz-Bernardino, Jesus		Active
Dennis, Kyle		Active
Diaz, Alejandro		Active

Dinh, Phan	[redacted]	Active
Do, Loc T		Active
Doan, Westy		Active
Dolan, Lisa		Active
Dominguez, Juanita		Active
Duell, Jennifer		Active
Ebal, Ruben		Active
Edwards, David W		Active
Egan, Kirsten		Active
Enero, Sherin		**LOA**
Escobar, Nelson A		Active
Espinoza, Jose R		Active
Fajardo, Marvin		Active
Flores-Gutierrez, Samara M		**LOA**
Fronda, Karen		Active
Gallegos Gomez, Blanca L		Active
Gallegos Gomez, Maricela		Active
Garcia, Cesar		Active
Garcia, Irma		Active
Garcia, Maria F		Active
Garcia, Rafael		Active
Garduno, Geraldine Rodriguez		Active
Garrison, Sarah M		Active
Garrison, Shireen M		Active
Gentry, Brandon		Active
Godinez Guillen, Ana L		Active
Golshanjou, Payam		Active
Gomez, Veronica		Active
Gonzalez, Emilio		Active
Grande Recinos, Jose		Active
Green, LaToya D		Active
Guerrero, Rosa M		Active
Gutierrez II, Robert A		Active
Guzman, Jose		Active
Guzman, Juan V		Active
Hall, Sandra		Active
Hammer-Smith, Marsha L		Active
Harper, Dan		Active
Hartloff, Timothy M		Active
Hendrycks, Paul		Active
Hicks, Dana K		Active
Hluan, Sung		Active
Hniang, Sung		Active
Houser, Madison		Active
Houser, Taylor N		Active
Huang, Chris		Active
Hudson, Angelic		Active
Hulse, Brandon		Active
Huynh, Thi Thuy Dung		Active
Huynh, Tuyet		Active
Ia, Ho K		Active
Iang, Ngun		Active
Jahla-Ebrahimi, Sina		Active
Johnson, Lammatta J		Active
Juarez, Silvia		Active
Kacvinsky, Joseph N		Active
Kain, Hannah		Active
Kapadia, Bhavnaben		**LOA**
Kaplenko, Lana		Active

Khatoon, Raziya	[redacted]	Active
Kieu, Diem Ngoc		Active
Kim, Nina		Active
Lam, Sen		Active
Lamar, Jasmine R		Active
Langley, Dillon		Active
Lara, Mireya		Active
Lastra Abad, Zeus		Active
Lazarit, Beneranda		Active
Le, Hang		Active
Le, Jefferson		Active
Le, Thi Tuyet Van		Active
Le, Thu		Active
Le, Yen		Active
Lee, Danielle		Active
Lee, Mina		Active
Leon Vera, Laura		Active
Lo, Alexander		Active
Lock, Geraldine		Active
Long, Lynette M		Active
Lopez Ruiz, Yajaira		Active
Lopez, Guadalupe		Active
Lopez, Jonathan		Active
Lowbridge, Fiona N		Active
Luu, Sang V		Active
Lwabanya, Josephine		Active
Ly, Kristy		Active
Madriaga, Johnny		Active
Madriz, Esmeralda		Active
Mang, J Bawi		Active
Mang, Tin Z		Active
Marquez Alberio, Cristian		Active
Marquez Morales, Itxel G		Active
Marquez, Maria		Active
Martin, Steven		Active
Martinez, Jocelyn		**LOA**
Marugg, Brandon		Active
Mejia, Albaro		Active
Mejia, Carlos J		Active
Mellen, Charisse		Active
Mihajlovski, Jordana		Active
Miller, Heather R		Active
Mojeed, Saheed		Active
Moore, Lamont		Active
Moraghebi, Kaveh		Active
Morrison, Pete		Active
Muldon, Arnold		Active
Murry, Ricky		Active
Mutabazi, Patrick		Active
Mvuyekure, John		Active
Nagashayana, Pallavi S		Active
Ngo, Son		Active
Nguyen, Chau T		Active
Nguyen, Huong		Active
Nguyen, Kim		Active
Nguyen, Manh		Active
Nguyen, Minh		Active
Nguyen, Thanh		Active
Nguyen, Thi Anh		Active

Nguyen, Thi Kim Cuong	[redacted]	Active
Nguyen, Thi Kim Hoa		Active
Nguyen, Thi Thuy Trang		Active
Nguyen, Tin V		Active
Nguyen, Tuan		Active
Nguyen, Virginia		Active
Nolasco, Rosemarie		Active
Ojeda, Sally J		Active
Olanrewaju, Gafar O		Active
Panchal, Pushpabahen H		Active
Pantoja, Monica		Active
Paolucci, Brooke A		Active
Parga, Ana M		Active
Partida, Adan		Active
Partida, Jose		Active
Partida, Nohemi		Active
Patel, Milan G		Active
Patel, Vanitha		Active
Pensa, Lyndelle		Active
Pensa, Mark		Active
Pequet, Elizabeth A		Active
Pham, Thi Thu Hang		Active
Phan, Huy		Active
Phan, John		Active
Phromsombath, Somsanouk		Active
Pierce, Steven		**LOA**
Pineda, Graciela		Active
Porter, Kenneth		Active
Ramirez, Silvia		Active
Rasmussen, Derek C		Active
Ray, Jonathan		Active
Redmond, Sammijo		Active
Reyes, Imelda		Active
Reyes-Perez, Andres		Active
Rivera Santiago, Genesis		Active
Rivera Santiago, Yajadi		Active
Rivera, Alexsa		Active
Roberts II, Martin		Active
Rodriguez, Maria Leticia		Active
Rodriguez, Monica		Active
Rodriguez, Rogelio		Active
Rodriguez, Sandra		Active
Rosales, Israel		Active
Sahakian, Rita		Active
Samra, Manpreet		Active
Sandoval, Magdalena R		Active
Santillan, Rosa		Active
Schaeffer, Mary		Active
Sexton, John K		Active
Sezgin, Burcu		Active
Shaffer, Danielle		Active
Short, Debra A		Active
Si, Bi		Active
Si, Pong		Active
Silva, Nora		Active
Singh, Kusum L		Active
Smith, Eric A		Active
Somerville, Kent		Active
Strickland, Tami		Active

Subramanian, Subu	[redacted]	Active
Sung, Par		Active
Surber, Martha		Active
Tang, Si		Active
Tawfeeq, Karwan		Active
Thai, Thi		Active
Thang, Mang		Active
Thompson, Michael D		Active
Thrasher, Cole E		Active
Tirado, Rosie V		Active
Todd, Michael		Active
Tolbert, Hannah M		Active
Toy, Julia		Active
Tran, Hoai T		Active
Tran, Holly H		Active
Tran, Huong T		Active
Tran, Huong T		Active
Trang, De		Active
Trivedi, Digeshbhai		Active
Trivedi, Nirali		Active
Truong, Duyen		Active
Truong, Lan T		Active
Ulloa, Alejandra		Active
Vagadori, Paul		Active
Valbuena, Sergio		Active
Viec, Thuy		Active
Vilchez, Juana		Active
Vo, Minh Lap		Active
Vo, Thi		Active
Wardak, Naquibullah		Active
Watson, Rich		Active
Whiting, David J		Active
Yim, Larry		Active
Youhanna, Michelle N		Active
Young, Christopher		Active
Zi, Ngai		Active

4E

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Section 1: General Information

Facility Name: Aphena Pharma Solutions - Tennesse, LLC

Physical Address: 1976 Chocolate Drive

City: Cookeville State: TN Zip: 38501

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

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

Telephone: 931-372-2041 Website: aphenapharma.com

Name of Designated Representative (DR): Jonathan Young

Licensing Company Email: LicenseTN@aphenapharma.com DR Email: jyoung@aphenapharma.com

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Nestle
Address: 2145 9th Avenue City: Ronkonkoma State: NY Zip: 11779

Name: R&S Northeast LLC AvKARE
Address: 10049 Sandmeyer Lane City: Philadelphia State: PA Zip: 19116

Name: Cardinal Health
Address: 7000 Cardinal Place City: Dublin State: OH Zip: 43017

Name: Tolmar Inc.
Address: 701 Centre Avenue City: Fort Collins State: CO Zip: 80526

Section 4: Publicly Traded Corporation

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

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee
Parent Company (if any): N/A
Corporation/Organization Name: Aphena Pharma Solutions - Tennessee, LLC
Mailing Address: 1976 Chocolate Drive
City: Cookeville State: TN Zip: 38501
Telephone: 931-372-2041 Email: LicenseTN@aphenapharma.com
Contact Person Name: John Kress

Section 6: Partnership

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

Section 7: Sole Owner

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

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	**Publicly Traded**	**Non-publicly Traded**	**Partner-ship**	**Sole Owner**
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Aphena Pharma Solutions - Tennessee, LLC

Facility Name

Jonathan Young

Print Name of Authorized Person Submitting Application

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

11/20/23

Date

Board Use Only	Date Received: 11/22/23	Amount: $1000 - Check 52705 ✓

Maria Herrera

From: John Kress <jkress@aphenapharma.com>
Sent: Friday, December 8, 2023 10:39 AM
To: Maria Herrera
Cc: LicenseTN
Subject: Re: Nevada Out-of-State Wholesaler Application-Aphena Pharma Solutions- Tennesse, LLC
Attachments: NV - Bond Rider.pdf; Employee List 12.8.2023.pdf

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

Hi Maria,

I've attached the bond rider and employee list. We are not going to wholesale medical devices, equipment, supplies, gases, etc. into NV.

Thanks,

Aphena
Pharma Solutions

John Kress
Aphena Pharma Solutions
QA Specialist

(931) 650-4248
jkress@aphenapharma.com
1920 Fisk Road
Cookeville, TN 38506
www.aphenapharma.com

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Friday, December 8, 2023 11:26 AM
To: LicenseTN <LicenseTN@aphenapharma.com>
Subject: Nevada Out-of-State Wholesaler Application-Aphena Pharma Solutions- Tennesse, LLC

The Nevada State Board of Pharmacy received an Out-of-State Wholesaler application from Aphena Pharma Solutions- Tennesse, LLC. The application is incomplete due to the following missing item(s).

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Aphena**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Aphena Pharma Solutions - Maryland, LLC	1130591	829739833	ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK;	7978 Industrial Park Road, Easton, Maryland (MD) 21601, United States (USA)	12/31/2023
Aphena Pharma Solutions - Tennessee, LLC	3003849479	128385585	LABEL; PACK; RELABEL; REPACK;	1920 Fisk Road, Cookeville, Tennessee (TN) 38506, United States (USA)	12/31/2023
Aphena Pharma Solutions - Tennessee, LLC	3003849479	118348161	LABEL; PACK; RELABEL; REPACK;	1976 Chocolate Drive, Cookeville, Tennessee (TN) 38501, United States (USA)	12/31/2023

Showing 1 to 3 of 3 entries
Previous1Next
Data Current through: Sunday, Nov 19, 2023

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Aphena Pharma Solutions Holdings, INC
Ownership Chart

Name of the Investor	% of ownership
Enhanced Healthcare Partners, LP	65.3%
Reliant PrePak	8.9%
David Stevens	7.0%
Andrew Paul	4.3%
Robert Allen	5.3%
Andrew Paul Family Holdings LLLP	2.3%
Kevin Kerchner	1.4%
Steven Hertzfeldt	1.3%
Kevin Bowling	1.8%
David Howe	0.6%
Joseph Del Buono	0.5%
Shawn Reilley	0.4%
Richard Brightman	0.2%
Dominick Montano	0.2%
Ronald Radwin	0.2%
Jon Kaiden	0.1%
Don Huggins	0.1%
Malcolm Kostuchenko	0.0%
	100.0%

Officers

- **Eric Allen – CEO**
- **Jonathan Young – COO**
- **Patrick Min – CFO**

Directors

- **Joseph Toussaint – Director of Quality**
- **Travis Jones – Director of Supply Chain & Engineering**
- **Lonnie Neal – Director of Operations**

0264

NABP ACCREDITED

DRUG DISTRIBUTOR

Aphena Pharma Solutions - Tennessee, LLC
dba Aphena Pharma Solutions

located at

1976 Chocolate Dr, Cookeville, TN 38506

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

11/29/2022 to 11/28/2025
Period of Accreditation

COPY

TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH RELATED BOARDS

ID NUMBER: 0000006641
EXPIRATION DATE: 09/30/2025

This is to certify that all requirements of the State of Tennessee have been met.

PHARMACY BOARD
THIRD PARTY LOGISTICS
APHENA PHARMA SOLUTIONS

COMMISSIONER OF HEALTH

COPY

APHENA PHARMA SOLUTIONS
TENNESSEE LLC
1976 CHOCOLATE DR
COOKEVILLE TN 38501-2022

13594254

33799

State of Tennessee
Department of Health

BOARD OF PHARMACY
THIRD PARTY LOGISTICS
APHENA PHARMA SOLUTIONS
TENNESSEE LLC
1976 CHOCOLATE DRIVE
COOKEVILLE TN 38501

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000006641
EXPIRATION DATE: 09/30/2025

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Rothaus, Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

COPY

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

PATRICK MIN
PATRICK MIN
1976 CHOCOLATE DRIVE
COOKEVILLE, TN 38501

August 7, 2023

Request Type: Certificate of Existence/Authorization
Request #: 0541530

Issuance Date: 08/07/2023
Copies Requested: 1

Document Receipt

Receipt # : 008292116 Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3856018926 $20.00

Regarding: **Aphena Pharma Solutions - Tennessee, LLC**

Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 07/19/2002
Status: Active
Duration Term: Perpetual
Business County: PUTNAM COUNTY

Control # : 430432
Date Formed: 07/19/2002
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

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

Aphena Pharma Solutions - Tennessee, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 062135617

GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: **Pharmaceutical Wholesaler**

Bond No.: **L271739-2142**

Dated effective: **11/14/2023**
(MONTH, DAY, YEAR)

executed by: **Aphena Pharma Solutions- Tennessee, LLC**, **as Principal,**
(PRINCIPAL)

and by: **Lexington National Insurance Corporation,** **as Surety,**
(SURETY)

and in favor of: **Nevada State Board of Pharmacy**
(OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal address for purposes of service	1920 Fisk Road Cookeville, TN 38506	1976 Chocolate Drive Cookeville TN 38506

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **11/30/2023**
(MONTH, DAY, YEAR)

Signed and Sealed **11/30/2023**
(MONTH, DAY, YEAR)

Aphena Pharma Solutions- Tennessee, LLC
PRINCIPAL

BY: _____
NAME AND TITLE

Lexington National Insurance Corporation
SURETY

BY: _____
Alexis Ryder, Attorney-in-Fact

TENNESSEE NOTARY ACKNOWLEDGEMENT

State of Tennessee

County of Davidson

Personally appeared before me, Trent Dillard (Name of Officer), Notary Public (Official Capacity of Officer), Alexis Ryder (Name of Person Executing Instrument), with whom I am personally acquainted, and who acknowledged that he or she executed the within instrument for the purposes therein contained. [THE FOLLOWING TO BE INCLUDED ONLY WHERE A NATURAL PERSON IS EXECUTING AS AGENT] and who further acknowledged that he or she is the Attorney-in-Fact (Title of Person acting as Agent) of the maker or a constituent of the maker and is authorized by the maker or by its constituent, the constituent being authorized by the maker, to execute this instrument on behalf of the maker.

Witness my hand, at office, this 30 day of November 2023.

Trent Dillard
Notary's Signature

Seal

My commission expires: 10/04/2027

IMPORTANT NOTICE – THIS POWER OF ATTORNEY IS VOID IF "LNIC Original" WATERMARK IS NOT PRESENT

POWER OF ATTORNEY
Lexington National Insurance Corporation

Lexington National Insurance Corporation, a corporation duly organized under the laws of the State of Florida and having its principal administrative office in Baltimore County, Maryland, does hereby make, constitute and appoint:

John Ecard Genet, Jr., Alexis Ryder, Nicholas Benenati

as its true and lawful attorney-in-fact, each in their separate capacity, with full power and authority to execute, acknowledge, seal and deliver on its behalf as surety any bond or undertaking of $6,000,000 or less. This Power of Attorney is void if used for any bond over that amount.

This Power of Attorney is granted under and by authority of the following resolutions adopted by the Board of Directors of the Company on February 15, 2018:

Be it Resolved, that the CEO, President or any Vice-President shall be and is hereby vested with full power and authority to appoint suitable persons as Attorney-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on the behalf of the Company, to execute, acknowledge and deliver any and all bonds, contracts, or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any all notices and documents cancelling or terminating the Company's liability thereunder and any such instruments so executed by any Attorney-in Fact shall be binding upon the Company as if signed by the CEO, President and sealed by the Corporate Secretary.

RESOLVED further, that the signature of the CEO, President or any Vice-President of LEXINGTON NATIONAL INSURANCE CORPORATION may be affixed by facsimile to any power of attorney, and the signature of the Secretary or any Assistant Secretary and the seal of the Company may be affixed by facsimile to any certificate of such power, or any such power or certificate bearing such facsimile signature or seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed with respect to any bond to which it is attached continue to be valid and binding upon the Company.

IN WITNESS WHEREOF, the Company have caused this instrument to be signed and their corporate seal to be hereto affixed.

Ronald A. Frank, CEO

State of Maryland
County of Harford County, SS:

Before me, a notary public, personally appeared, Ronald A. Frank, CEO of Lexington National Insurance Corporation, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under the PENALTY of PERJURY under the laws of the State of Maryland that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Commission Expires: 05/23/24

Notary

I, Lisa R. Slater, Secretary of Lexington National Insurance Corporation, do hereby certify that the above and foregoing is true and correct copy of a Power of Attorney, executed by said company, which is still in full force and effect; furthermore, the resolutions of the Boards of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Baltimore, Maryland this 12th day of June, 2023.

Lisa R. Slater, Secretary

Attached to bond signed this 30th day of November, 20 23

F:\lnic\Power of Attorney form CS 2021 with Watermark Seal

NEVADA STATE BOARD OF PHARMACY

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

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. L271739-2142

Application/License No. N/A

Aphena Pharma Solutions-Tennessee, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1920 Fisk Road Cookeville, TN 38506 (Address of Applicant/Principal), as PRINCIPAL, and Lexington National Insurance Corporation (Surety Company), a corporation organized under the laws of the state of Florida (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is PO Box 6098, Lutherville, MD 21094 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 14, 2023 (Effective Date).

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

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 14th day of November, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Alexis Ryder, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

MELISSA DODSON
STATE OF TENNESSEE NOTARY PUBLIC
PUTNAM COUNTY

My Commission Expires February 21, 2024

Countersigned by:

Nevada Resident Agent

IMPORTANT NOTICE – THIS POWER OF ATTORNEY IS VOID IF "LNIC Original" WATERMARK IS NOT PRESENT

POWER OF ATTORNEY
Lexington National Insurance Corporation

Lexington National Insurance Corporation, a corporation duly organized under the laws of the State of Florida and having its principal administrative office in Baltimore County, Maryland, does hereby make, constitute and appoint:

John Ecard Genet, Jr., Alexis Ryder, Nicholas Benenati

as its true and lawful attorney-in-fact, each in their separate capacity, with full power and authority to execute, acknowledge, seal and deliver on its behalf as surety any bond or undertaking of $6,000,000 or less. This Power of Attorney is void if used for any bond over that amount.

This Power of Attorney is granted under and by authority of the following resolutions adopted by the Board of Directors of the Company on February 15, 2018:

Be it Resolved, that the CEO, President or any Vice-President shall be and is hereby vested with full power and authority to appoint suitable persons as Attorney-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on the behalf of the Company, to execute, acknowledge and deliver any and all bonds, contracts, or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any all notices and documents cancelling or terminating the Company's liability thereunder and any such instruments so executed by any Attorney-in Fact shall be binding upon the Company as if signed by the CEO, President and sealed by the Corporate Secretary.

RESOLVED further, that the signature of the CEO, President or any Vice-President of LEXINGTON NATIONAL INSURANCE CORPORATION may be affixed by facsimile to any power of attorney, and the signature of the Secretary or any Assistant Secretary and the seal of the Company may be affixed by facsimile to any certificate of such power, or any such power or certificate bearing such facsimile signature or seal shall be valid and binding on the Company. Any such power so executed and sealed and certified by certificate so executed and sealed with respect to any bond to which it is attached continue to be valid and binding upon the Company.

IN WITNESS WHEREOF, the Company have caused this instrument to be signed and their corporate seal to be hereto affixed.

LEXINGTON NATIONAL INSURANCE CORPORATED 1989 FLORIDA

Ronald A. Frank, CEO

State of Maryland
County of Harford County, SS:

Before me, a notary public, personally appeared, Ronald A. Frank, CEO of Lexington National Insurance Corporation, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under the PENALTY of PERJURY under the laws of the State of Maryland that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Commission Expires: 05/23/24

ALYSSA BARNES NOTARY PUBLIC HARFORD COUNTY, MD

Notary

I, Lisa R. Slater, Secretary of Lexington National Insurance Corporation, do hereby certify that the above and foregoing is true and correct copy of a Power of Attorney, executed by said company, which is still in full force and effect; furthermore, the resolutions of the Boards of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Baltimore, Maryland this 12th day of June, 2023.

Lisa R. Slater, Secretary

Attached to bond signed this 14th day of November, 2023

F:\lnic\Power of Attorney form CS 2021 with Watermark Seal

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Aphena Pharma Solutions - Tennessee, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 1976 Chocolate Drive

City: Cookeville State: TN Zip: 38501

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

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

Telephone: 931-372-2041 Website: aphenapharma.com

Licensing Company Email: licenseTN@aphenapharma.com

Section 2: Personal Information

First: Jonathan Middle: Alan Last: Young

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

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

Mailing Address: [redacted]

City: Cookeville State: TN Zip: 38501

Telephon[redacted] Email: jyoung@aphenapharma.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
University of Phoenix			08/02-09/04	
Address		City	State	Zip
4035 S Riverpoint Pkwy		Phoenix	AZ	85040
Diploma/Degree obtained, if any				
MBA				
School Name			From - To (MM/YY – MM/YY)	
Rochester Institute of Technology			09/85-05/90	
Address		City	State	Zip
One Lomb Memorial Dr		Rochester	NY	14623
Diploma/Degree obtained, if any				
BSME				
School Name			From - To (MM/YY – MM/YY)	
Saunders Trades and Technical HS			09/80-06/85	
Address		City	State	Zip
183 Palmer Road		Yonkers	NY	10701
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20-Present	[redacted]	Cookeville	TN	38501
06/20-09/20		Cookeville	TN	38506
12/18-9/20		Greenville	NC	27834
09/18-12/18		Greenville	NC	27834
01/02-09/18		Allentown	PA	18104
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Aphena Pharma Solutions			06/20-Present	
Business Address		**City**	**State**	**Zip**
1976 Chocolate Dr		Cookeville	TN	38501
Phone	**Title**		**Number of Employed Hours**	
931-651-6814	COO		7120	
Description of Duties				
Oversee all pharmaceutical operations for Rx, OTC, medical device and biologic kitting.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Jonathan Young, **certify that as the designated representative for**

Aphena Pharma Solutions - Tennessee, LLC,

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

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

Jonathan Young

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/7/23

Date

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

Jonathan Young

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/7/23

Date

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

State of TN, ss. County of PUTNAM

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

Original Signature

11/7/23

Date

Subscribed and Sworn to before me this 7 day of November 2023

Notary Public Signature

My Commission Expires February 21, 2024

MELISSA DODSON STATE OF TENNESSEE NOTARY PUBLIC PUTNAM COUNTY

(Seal)

Employee_Name	Employee_Name	Employee_Name	Employee_Name
ABRAMS, DIANE M	DENNIS, FREDDIE B	KNIGHT, CHARITY A	REAGAN, SHAWN D
ADAMS, COLE	DIAL, LESLIE JADE	KNIGHT, DAVID A	REECE, KAYLA J
ALCORN, JENNY C	DIAZ, MELISSA ANN	KNIGHT, JERRY L	RICH, CRYSTAL L
ALLEN, CYNTHIA L	DILLDINE, JAMMIE DALE	KRESS, JOHN MICHAEL	RICH, ROBERT EUGENE
ALLEN, ERIC	DILLON, ALYICIA A	KROLL, PAUL ALEXANDER	RICH, TRAVIS D
ALLEN, JAMIE R	DISHMAN, DWAYNE	LAFEVER, MARY K	RICH, WAYNE M
ALLISON, JAMES TIMOTHY	DIXON, TERRI A	LAFEVER, MELISSA D	ROBERTS, FRANK EUGENE
ALLISON, ROBERT GREG	DONOHUE, TIA MARIE	LAMB, JONATHAN L	ROGERS, CHRISTOPHER ADAM
ALVAREZ LOPEZ, HEISI ZIRA	DOWIS, ELYSA MICHELE	LEDBETTER, PAMELA DIANE	ROOK, AMANDA
ANDERSON, JESSICA D	DYER, KATHALYNE MODENA	LEON-ALVAREZ, LYDIANNA	ROURKE, THELMA CONNIE
ANDERSON, JULIET E	ELROD, JUDY GAIL	LEWIS, ROBERT TYRONE	RUBLE, KEVIN D
ARMS, GARY WAYNE	EMRICH, KEITH H	LINDER, LARRY J	SALINAS-CHAVEZ, RAFAEL
ASPROGIANNIS, AUDREY PHILLIPS	EVELETH, WILLIAM T	LITCHFORD, GABRIEL W	SAVAGE, ELDON J
ASPROGIANNIS, JAMES ALLEN	FARNSWORTH, AUSTIN MICHAEL	LITTLE, JAMIE S	SAVAGE, SABRA L
BAKER, RONALD LEE	FARRIS, BILLY JOE	LOWERY, ROBIN L	SCHAEFER, JUSTIN L
BARBER, BRIAN D	FLANNERY, SHARON F	LUTTRELL, NATHAN A	SCHUMANN, JEFFREY L
BARNETT, MARK SHANE	FLETCHER, ELLA G	LYNN, DAVID WAYNE	SEBER, ANTHONY B
BARNETT, RANDI LYNN	FRANCISCO, ISRAY	MABE, CHAD E	SELLS, BRIAN S
BARRETT, LISA J	FREY, HERLINA R	MABERY, BARBARA	SEPHERS, LANDON RENE
BENNETT, ANTHONY D	GARRETT, JESSICA RANA	MADRAZO, ARVI GUTIERREZ	SERRANO LOPEZ, TERESA
BERRY, LOREN S	GARRETT, SANDRA L	MANIS, TINA M	SHERWOOD, SHAE
BESAW, WENDY L	GEER, NARCISA NOLIA	MANSELL, TIFFANY R	SHIRLEY, BRYAN TYLER
BIRDWELL, DONALD W	GENTRY, JESSICA E	MARSHALL, GAVIN DANTE	SHOBE, LISA K
BLACKMON, PATTY A	GERMAIN, JUDY A.	MARTIN, DONNA	SIMMONS, TITUS
BOLES, RAY N	GIBSON, ANITA S	MATIAS BALTAZAR, REYNALDO DIEGO	SIMPSON, VIRGINIA D
BOUSLOG, SKYLER T	GILLESPIE, KIMBERLY D	MAYBERRY, DAVID MICHAEL	SIMS, ELANA S
BOWERS, JASON P	GLINTENKAMP, PAUL MICHAEL	MCALISTER, MELISSA DAWN	SMITH, CHLOE
BOWERS, JED A	GOLDEN, DEANNA	MCDONALD, JOSEPH SCOTT	SMITH, KEVIN LEN
BOYER, MALISSA MAE	GRANT, LISA G	MCDONALD, LESIA Y	SMITH, PAULA JEAN
BOYKIN, GWENDOLENE DORTHEA	GREER, RICKEY RANDALL	MCKELVEY, JORDAN R	SNYDER, KATHRYN ELIZABETH
BRECKER, GARY WAYNE	GUTIERREZ, JAIMIE	MCMURRY, MARCUS A	SPARKS, RONNIE E
BROOKS, JUDY C	HANEY, ALLISON R	MELHOUSE, BRETT EDWARD	SPIVEY, KALIN J
BROWN, DANA NICHOLE	HANEY, BRIAN L	MEREDITH, GARY TODD	STAFFORD, STEVEN EDWARD
BROWN, MANDI M	HARGROVE, FRANK MATTHEW	MILLER, KISHA ARLENE	STEWART, SHAWN WILLIAM
BROWN, MATT WAYNE	HATLEY, GEORGE A	MILLER, WANDA G	STINSON, BRITTNEY NICOLE
BROWN, RAY	HAWN, GLENDA C	MIN, PATRICK	SWAFFORD, SONJA DANIELL
BROWN, ROBERT S.	HAWN, REBECCA ANN	MOORE, JEFFREY L	SWEEZY, TAYLOR LEANN
BROWN, TRACEY J	HEATH, JEFFRY P	MOSS, JEFFERY R	TABORS, JACOB WAYNE
BULLOCK, SHEILA R	HENRY, ANDREW E	MULLINS, KARLEIGH ELIZABETH	TAYES, DAVID S
BURNS, KAYCEE VERNES	HEUVING, MICHELE	MURPHY, LISA G	TAYLOR, MELISSA K
CAPERS, SHILOH FRANCES	HICKS, ADAM L	NABORS, CAROLYN SUE	THARP, TONY G
CARMONA, JOSE LUIS	HILL, PAM	NEAL, LONNIE R	THOMASON, MIRANDA R
CASH, SARAH L	HILLIS, CODY JARED	NEAL, RHONDA L	THRASHER, CHARLES EDWARD
CASTLE, JEREMY PAUL	HILLIS, KIMBERLY L	NORRIS, KAREN KAY	TOLLETT, MARCUS L
CHOATE, CHERI DAWN	HOLMES, DAVID C	OAKS, LISA CHRISTINE	TOUSSAINT, JOSEPH H
CIRIGO, CARLOS ALONSO	HOOTEN, ROBYNN D	PACHALLA, RAMESH B	TRAPP, LANDY MICHAEL
CLIFTON, SHAYLA MICHOLE	HOWELL, AMARILIS	PARRISH, CAROLYN S	TROBAUGH, MALISSA L
COLBURN, BRADLEY S	HOWELL, JAMES K	PATRICK, JENNIFER ROBIN	VAUGHN, MARCY JEAN
COLEMAN, ANGELA MARIE	ICEMAN, PATTI ANN	PAYNE, JUSTIN	WALKER, JENNIFER LOUISE
COLSON, CASSANDRA CHAVIS	JAMES, SHERI M	PEDIGO, JAMES D	WALLACE, JEFFREY LANE
CONATSER, LARRY L	JOHNSON, DESTINY BELLE	PETERS, SCOTT E	WATTS, JOANN
CONTRERAS, DEVANTE J	JOHNSON, JEREMIAH DANIEL	PHILLIPS, HONEYLEEN BUENAFE	WATTS, LINDA D
COVERT, PAMELA JILL	JOHNSON, MELISSA G	PHILLIPS, LEISA	WEAVER, CHEYENNE ANTIONETTE
COWAN, JORDON ALEX	JONES, KIMBERLY D	PIERCY, ROGER LEE	WELCH, AMY L
COX, RACHEL RENEE	JONES, RENESIA ROSE	PITTMAN, ADDISON LEE	WELLS, ALEX J
CRABTREE, JAMES BOYD	JONES, TRAVIS M	POSEY, ADAM A	WILDER, SHELBY LYNN
CRONE, JENIFER LYNN	JUAN, HECTOR FELIPE	PRATER, COLBY TERRANCE	WILLIAMS, ANDREW CLAY
DAILEY, JOHNNY	JUAN, MIGUEL BARTOLOME	PRICE, JACOB T	WINNINGHAM, SAMANTHA ANN
DARRAH, CAROLINE J	KALAL, MARK ROBERT	QUALLS, MELINDA KAY	YOUNG, JONATHAN A
DAUGHERTY, ORVAL RANDELL	KEMP, CARL D	RAGLAND, JOSHUA	YOUNG, SANDY C
DAVIS, NICOLAS	KEYTON, COLIN C	RANDOLPH, DALTON C	YOUNGS, DANIELLE MARIE
DAY, SHERRI L	KINNAIRD, JUSTIN C	REAGAN, JAMES K	

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02812	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: BE Pharmaceuticals, Inc.

Physical Address: 203 New Edition Court

City: Cary State: NC Zip: 27511

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.biologicale.com

Name of Designated Representative (DR): David Kauffman Sanford

Licensing Company Email: BEP@SLSNY.com DR Email: david.sanford@biologicale.com

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

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

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

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
06/08/2023		AR		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2023-065	Arkansas State Board of Pharmacy

Reason/Charge

Failure to notify the board within the required 14 days of a Change of Ownership

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

Name of Business/Industry/Entity

BE Pharmaceuticals, Inc.

Provide explanation below:

Please see the attached consent Agreement discipline docs.

Original Signature (electronic, copies or stamps not accepted)

11/13/23
Date

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

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/14/2023		AL		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
23-L-0223	Alabama State Board of Pharmacy

Reason/Charge

Failing to notify the board within 10 days of any change in ownership

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

Name of Business/Industry/Entity

BE Pharmaceuticals, Inc.

Provide explanation below:

Please see attached Discipline-Pending Docs

Original Signature (electronic, copies or stamps not accepted)

11/13/23

Date

AR- Resolved

0286

Arkansas State Board of Pharmacy

322 South Main Street, Suite 600 Little Rock, AR 72201
P: 501.682.0190 F: 501.682.0195
asbp@arkansas.gov • www.pharmacyboard.arkansas.gov
John Clay Kirtley, Pharm.D., Executive Director

October 16, 2023

BE Pharmaceuticals, Inc.
203 New Edition Court
Cary, NC 27511

Case No: 2023-065

Dear Sir/Madam:

Enclosed please find the executed Consent Agreement in the above-styled case. If you have any questions, please contact the Board office at 501-682-0190

Sincerely yours,

Ashley Vailes
General Counsel

RECEIVED
ARKANSAS STATE
BOARD OF PHARMACY

BEFORE THE ARKANSAS STATE BOARD OF PHARMACY

IN THE MATTER OF
BE Pharmaceuticals, Inc.
WD05295

CASE # 2023-065

CONSENT AGREEMENT

WHEREAS, Respondent **BE Pharmaceuticals, Inc.,** located in Cary, NC, is licensed as a wholesale distributor of prescription drugs and holds license WD05295;

WHEREAS, a change of ownership occurred on March 21, 2023. The Board did not receive notification from Respondent **BE Pharmaceuticals, Inc.** of said change of ownership until April 21, 2023.

WHEREAS, BE Pharmaceuticals, Inc. may be charged with violations of Board Regulation 08-00-0003 and A.C.A. §17-92-407, and § 17-92- 315;

WHEREAS, Respondent makes no admission of guilt but wishes to resolve these charges informally. By entering into this non-disciplinary Consent Agreement, Respondent's statements herein shall not be used as evidence in a formal hearing if this agreement is not accepted by the Board. Respondent and the Board therefore agree that this Agreement shall not constitute disciplinary action but rather an informal resolution of these charges. Respondent expressly waives its right to an administrative hearing and consents to the terms incorporated in this Agreement. Respondent further consents to the *ex parte* presentation of this Agreement to the Board and agrees that, if the Agreement is not accepted by the Board, the presentation and consideration of this Consent Agreement by the Board shall not constitute a basis for disqualification of the Board or any of its members from further participation in this matter, including a formal hearing; and

WHEREAS, Respondent acknowledges that this Consent Agreement is not effective until its acceptance by the Board, that Respondent has had the opportunity to consult with legal counsel of its own choosing concerning the advisability, meaning and effect of this Consent Agreement, that the Board shall retain jurisdiction to enforce the provisions of this Consent Agreement, and that failure to comply with the terms and conditions of this agreement shall be grounds for disciplinary action in the form of a civil penalty and/or suspension or revocation of Respondent's license, registration or permit.

THEREFORE, Respondent consents to the following terms in full resolution of this complaint:

1. Respondent **BE Pharmaceuticals, Inc. (WD05295)** willingly agrees and stipulates that it shall pay a non-disciplinary investigative cost of two thousand five hundred dollars ($2,500.00) to the Board on or before August 15, 2023.

EXECUTED this 24 day of July, 2023

(David Sanford)

Authorized Representative of BE Pharmaceuticals, Inc.
Respondent

Attorney for Respondent (Optional)

John Clay Kirtley
Executive Director
Arkansas State Board of Pharmacy

President
Arkansas State Board of Pharmacy

OCT 10 2022
ARKANSAS STATE
BOARD OF PHARMACY

DocuSign Envelope ID: F99516C4-4968-4E83-AFC0-F888068615A5

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
BE PHARMACEUTICALS, INC.	)	
	)	**CASE NO.: 23-L-0223**
Private Label Distributor (Virtual)	)	
Permit No.: 195863	)	

DEFERRAL AGREEMENT

This Agreement is entered into by and between the Alabama State Board of Pharmacy (Board) and BE Pharmaceuticals, Inc.

WHEREAS, BE Pharmaceuticals, Inc. was served with a Statement of Charges and Notice of Hearing (Pending Charges) alleging violations of the Alabama Pharmacy Practice Act. A copy of the Pending Charges is attached hereto as Exhibit "A".

WHEREAS, the parties, through counsel, have engaged in discussions concerning an informal resolution of the Pending Charges.

WHEREAS, the parties have agreed to resolve these matters pursuant to Code of Alabama (1975) 41-22-12(f) by their approval of the following terms:

IT IS THE THEREFORE UNDERSTOOD AND AGREED BY THE PARTIES AS FOLLOWS:

1. The Pending Charges against BE Pharmaceuticals, Inc. shall be deferred until December 31, 2023 (Deferral Period).

2. As a condition to the Deferral described above, BE Pharmaceuticals, Inc. shall pay administrative costs in the amount of two thousand dollars ($2,000) within thirty (30) days of the effective date of this Agreement, that being the date it is signed on behalf of the Board. Failure to pay this amount shall be considered a probable cause violation BE Pharmaceuticals, Inc. as defined below. This payment shall not be subject to discharge in bankruptcy nor shall BE Pharmaceuticals, Inc. attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village 5treet, Birmingham, Alabama 35242.

3. In the event there are no probable cause violations of the Alabama Pharmacy Practice Act involving BE Pharmaceuticals, Inc. during the Deferral Period set forth above, the Pending Charges shall be dismissed.

4. In the event there is a probable cause violation of the Alabama Pharmacy Practice Act involving BE Pharmaceuticals, Inc. during the Deferral Period set forth above, both the Pending Charges and any new charges shall be noticed and scheduled for a hearing.

5. Neither the Pending Charges nor this Agreement shall be reported as discipline as long as BE Pharmaceuticals, Inc. complies with the conditions of Paragraphs Two and Three of this Agreement.

6. If there are no probable cause violations at the end of the Deferral Period, BE Pharmaceuticals, Inc. expressly waives its right pursuant to the Alabama Pharmacy Practice Act, and the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to Code of Alabama (1975), §34-23-92(12), Code of Alabama (1975), §41-22-12 and §41-22-20, and including but not limited to the opportunity for a hearing before the Board in connection with the Pending Charges against it and any judicial review. BE Pharmaceuticals, Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Deferral Agreement, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

7. By execution of this Deferral Agreement, BE Pharmaceuticals, Inc. hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Deferral Agreement and Pending Charges.

8. BE Pharmaceuticals, Inc. acknowledges and agrees that it has read this Deferral Agreement and that it fully understands the terms, conditions and contents of the same. BE Pharmaceuticals, Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Deferral Agreement and acknowledges that it had the right to seek advice of counsel before executing this Deferral Agreement.

DONE this the 23rd day of October, 2023.

Jennifer Muro Neumann
Jennifer Muro Neumann, P.C.
Post Office Box 381082
Birmingham, Alabama 35238

Robert M. Colburn, Jr., R. Ph.,
President
State Board of Pharmacy

DONE this the 19th day of October, 2023.

BE Pharmaceuticals, Inc.

By: David Sanford

Its: SVP US Commercial Operations

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

Name: Amerisourcebergen
Address: 1 West First Ave City: Conshohoken State: PA Zip: 19428

Name: Cardinal Health
Address: PO Box 182516 City: Columbus State: OH Zip: 43218

Name: McKesson Drug Co
Address: PO Box 4017 City: Danville State: IL Zip: 61834

Name: Amerita, Inc.
Address: 5299 DTC Blvd, Unit 900 City: Greenwood Village State: CO Zip: 80112

Section 4: Publicly Traded Corporation

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

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): BE Pharmaceuticals AG - 100%
Corporation/Organization Name: BE Pharmaceuticals, Inc.
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: BEP@SLSNY.com
Contact Person Name: Christine Cannon

Section 6: Partnership

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

Section 7: Sole Owner

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

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 71839	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-Publicly Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - 100% sole ownership		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A - No MDEG	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A - No MDEG	✓	✓	✓	✓
N/A **Only complete below if your company is NOT accredited by NABP and/or not registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

BE Pharmaceuticals, Inc.

Facility Name

David Kauffman Sanford

Print Name of Authorized Person Submitting Application

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

11/08/23

Date

Board Use Only	Date Received: 11/27/23	Amount: $1000 - check 50124 ✓

Proof of Assigned labeler code NDC 71839

/ NDC (index.cfm)

National Drug Code Directory

Current through November 21, 2023

You have searched Finished drug products

Search Results: *'BE Pharmaceuticals'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

	Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
-	CARBOPROST TROMETHAMINE	71839-137-10	250 ug/mL	INJECTION, SOLUTION	INTRAMUSCULAR	ANDA216882	BE Pharmaceuticals Inc.	71839-137	carboprost tromethamine	CARBOPROST TROMETHAMINE	HUMAN PRESCRIPTION DRUG	05/11/2023	N/A
+	daptomycin	71839-107-01	500 mg/10mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA212513	BE Pharmaceuticals Inc.	71839-107	daptomycin	DAPTOMYCIN	HUMAN PRESCRIPTION DRUG	06/26/2019	N/A
-	daptomycin	71839-108-01	350 mg/7mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA213425	BE Pharmaceuticals Inc.	71839-108	daptomycin	DAPTOMYCIN	HUMAN PRESCRIPTION DRUG	08/20/2020	N/A
-	daptomycin	71839-108-10	350 mg/7mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	ANDA213425	BE Pharmaceuticals Inc.	71839-108	daptomycin	DAPTOMYCIN	HUMAN PRESCRIPTION DRUG	08/20/2020	N/A
+	enoxaparin sodium	71839-109-10	30 mg/.3mL	INJECTION	SUBCUTANEOUS	ANDA214646	BE Pharmaceuticals Inc.	71839-109	enoxaparin sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A
+	enoxaparin sodium	71839-110-10	40 mg/.4mL	INJECTION	SUBCUTANEOUS	ANDA214646	BE Pharmaceuticals Inc.	71839-110	enoxaparin sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A
-	enoxaparin sodium	71839-111-10	60 mg/.6mL	INJECTION	SUBCUTANEOUS	ANDA214646	BE Pharmaceuticals Inc.	71839-111	enoxaparin sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A
+	enoxaparin sodium	71839-112-10	80 mg/.8mL	INJECTION	SUBCUTANEOUS	ANDA214646	BE Pharmaceuticals Inc.	71839-112	enoxaparin sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A
+	enoxaparin sodium	71839-113-	100 mg/1mL	INJECTION	SUBCUTANEOUS	ANDA214646	BE Pharmaceuticals Inc.	71839-113	enoxaparin sodium	ENOXAPARIN SODIUM	HUMAN PRESCRIPTION DRUG	06/16/2023	N/A

BE Pharmaceuticals, Inc.

Corporate Address: 203 New Edition Court, Cary, NC 27511 USA
FEIN: 83-2475854
www.biologicale.com

Drug Labeler Code: 71839
Incorporation State: DE
Incorporation Date: 10/12/2018

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
NEC	203 New Edition Court Cary, NC 27511 County: Wake			08-149-9296	No	(919) 545-1159	(919) 762-6210

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
David Kauffman Sanford	[redacted]	Senior Vice President	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
BE Pharmaceuticals AG	Bundesstrasse 3 Zug Zug, 6302 Switzerland	N/A	100%	N/A	CHE -163.345.959	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
William Maas Hill IV	[redacted]	President	No	[redacted]		
David Kauffman Sanford		Senior Vice President	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Cardinal Health 105, LLC. dba Specialty Pharmaceutical Services	15 Ingram Blvd Lavergne,, TN 37086					

Company Particulars & Ownership info

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BE Pharmaceuticals, Inc.

Pharmacy/Wholesaler License # (if applicable) WH02812

Physical Address 203 New Edition Court

City Cary State NC Zip 27511

Mailing Address (if different from physical address) c/o State License Servicing 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website www.biologicale.com

Licensing Company Email BEP@SLSNY.com

Section 2: Personal Information

First David Middle Kauffman Last Sanford

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

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

Mailing Address [redacted]

City Cary State NC Zip 27518

Telephone [redacted] Email david.sanford@biologicale.com

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

Section 3: Military Service (NRS 622.320)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 630.125)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

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

School Name	From - To (MM/YY – MM/YY)		
Ohio State University	2005 - 2007		
Address	City	State	Zip
281 W Lane Ave	Columbus	OH	43210
Diploma/Degree obtained, if any			
Masters Business Administration			

School Name	From - To (MM/YY – MM/YY)		
Centre College	1993 - 1997		
Address	City	State	Zip
600 W Walnut St	Danville	KY	40422
Diploma/Degree obtained, if any			
BA Economics			

School Name	From - To (MM/YY – MM/YY)		
The Columbus Academy	1988 - 1992		
Address	City	State	Zip
4300 Cherry Bottom Road, PO Box 42	Gahanna	OH	43230
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2014 - Present	[redacted]	Cary	NC	27518
06/2011 - 06/2014		Sylvania	OH	43560
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacy (NAC 639.5005) and/or wholesalers (NAC 639.[illegible]) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
BE Pharmaceuticals, Inc.		03/2019 - Present
Business Address	**City**	**State / Zip**
203 New Edition Court	Cary	NC 27511
Phone	**Title**	**Number of Employed Hours**
(919) 545-1159	Senior Vice President	~ 9,531 hrs

Description of Duties

Dynamic, enthusiastic and versatile professional with over 20 years of experience in customer facing functions within the pharmaceutical industry. 15 years managing exempt and non-exempt employees. Responsible for maintaining national distribution centers located through out the entire US with shipments all over the US and internationally. Versed in all aspects of the pharmaceutical industry - direct experience includes; drug wholesaler, drug packager, national chain pharmacy and Rx/OTYC drug manufacturer.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, David Kauffman Sanford, **certify that as the designated representative for**

BE Pharmaceuticals, Inc.,

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

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

David Kauffman Sanford
Print Name (First, Last)

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

11/08/23
Date

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

David Kauffman Sanford

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/08/23

Date

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

State of NC, ss. County of Wake

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

Original Signature David Kauffman Sanford

11/08/23

Date

NC, Wake County

Subscribed and Sworn to before me this 8th day of Nov 2023.

Notary Public Signature

NATVARLAL C. PRAJAPATI NOTARY PUBLIC WAKE COUNTY NC MY COMMISSION EXPIRES 10/29/2025

(Seal)

Employee List

BE Pharmaceuticals Inc.

BE Employees 09/06/2022

1) Narender Mantena – CEO
2) William Maas Hill IV – President
3) David Sanford – SVP US Commercial Operations
4) Will Baskervill – Director Finance
5) Chris Johnson - Director of Sales
6) Diane DeMoura – Manager Sales Operations
7) Jake Neumann – Finance Analyst

Officer List

BE Pharmaceuticals Inc.

To Whom It May Concern:

As of this date, I hereby certify that the following individuals serve as officers of BE Pharmaceuticals Inc.:

William Hill, President

David Sanford, Senior Vice President

Treasurer – Vacant

Secretary - Vacant

Signed,

_08/17/22_

David Sanford Date

Senior Vice President BE Pharmaceuticals, Inc

Incorp Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BE PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BE PHARMACEUTICALS, INC." WAS INCORPORATED ON THE TWELFTH DAY OF OCTOBER, A.D. 2018.

Jeffrey W. Bullock, Secretary of State

7099093 8300

SR# 20233923833

Authentication: 204554549

Date: 11-08-23

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

Home State (NC) online Verification of License Virtual Manu

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: BE PHARMACEUTICALS INC

Address: 203 NEW EDITION COURT CARY, NC 27511

License Type: Virtual Manufacturer

License Number: 1579

Status: Active - in good standing

Discipline: No

Issue Date: 11/7/2023

Original Issue: 7/10/2019

Expiration Date: 12/31/2024

Home State (NC) Online Verification of License Distributor

https://apps.ncagr.gov/agrsysportal/publiclicensesearch/CoursesPrintable?LID=400389 11/9/2023

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: BE PHARMACEUTICALS INC

Address: 203 NEW EDITION COURT CARY, NC 27511

License Type: Distributor

License Number: 532

Status: Active - in good standing

Discipline: No

Issue Date: 11/7/2023

Original Issue: 7/10/2019

Expiration Date: 12/31/2024

Home State (NC) No official Verification of License Letter

Smason replied

4 months ago (Wed, 20 May 2020 at 12:19 PM)

To: "SLSNYSupport.com" <help@slsnysupport.com>

You may retrieve your permit verification from our website, we do not generate letters, and haven't for years, now. Additional questions regarding verifications should be directed to Leslie Wilson, lwilson@ncbop.org . Thanks!

Regards,

Stacie P. Mason
Licensing Specialist
North Carolina Board of Pharmacy
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517
919-246-1050
smason@ncbop.org
www.ncbop.org
Twitter: @ NCBOP_Students

This e-mail message and any replies potentially are subject to disclosure under the Public Records Law and therefore could be disclosed to third parties.

VERIFICATION CERTIFICATE

THIS IS TO CERTIFY that Bond No. 0774308 issued by

HARCO NATIONAL INSURANCE COMPANY

dated the 14TH day of FEBRUARY, 2023,

in the amount of ONE HUNDRED THOUSAND and No/100-----($100,000.00),

on behalf of BE PHARMACEUTICALS, INC.
(as Principal),
and in favor of STATE OF NEVADA (as Obligee),

covers a term which began on the 14TH day of FEBRUARY, 2023, and

ends only with the cancellation of said bond or other legal termination thereof; and that the

said bond remains in effect, subject to all its agreements, conditions and limitations.

*Signed, sealed and dated
03/28/23

*Use current or renewal date.

HARCO NATIONAL INSURANCE COMPANY

By: _____
D. JOSEPH, Attorney-in-Fact

POWER OF ATTORNEY

Bond # 0774308

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 702 Oberlin Road, Raleigh, North Carolina 27605

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

LINDA C. SHEFFIELD, CONWAY C. MARSHALL, STEPHEN BEAHM, DAVID C. JOSEPH, JESSICA PALMERI, ROXANNE CRAVEN, ANDREA BECKER, CLARK P. FITZ-HUGH, DARLENE A. BORNT, CATHERINE C. KEHOE, KRISTINE DONOVAN, ELIZABETH W. KEARNEY

New Orleans, LA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2018

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2018 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC No. 50079919 NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day. March 28, 2023

A00586

Irene Martins, Assistant Secretary

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: DMG America, LLC

Physical Address: 242 South Dean Street

City: Englewood State: NJ Zip: 07631

Mailing Address (if different from physical address): Same as physical.

City: _____ State: _____ Zip: _____

Telephone: 201-894-5505 Website: www.dmg-america.com

Name of Designated Representative (DR): Donna Morris

Licensing Company Email: dmorris@dmg-america.com DR Email: dmorris@dmg-america.com

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: Medical Products Laboratories
Address: 9990 Global Road City: Philadelphia State: PA Zip: 19115
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

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

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: LLC formed in New Jersey
Parent Company (if any): Alpha Dentalhandelsgesellschaft MBH & Co KG
Corporation/Organization Name: DMG America, LLC
Mailing Address: 65 Challenger Rd, Suite 340
City: Ridgefield Park State: NJ Zip: 07660
Telephone: 201-894-5505 x317 Email: pcrawford@dmg-america.com
Contact Person Name: Patrick Crawford

Section 6: Partnership

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

Section 7: Sole Owner

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

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

DMG America, LLC

Facility Name

Patrick Crawford, Vice President of Finance

Print Name of Authorized Person Submitting Application

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

11-13-2023

Date

Board Use Only	Date Received: 12/7/23	Amount: $1000-check 50643

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
DMG America LLC
Business Trade Name:
DMG America LLC DBA: Goldsmith & Revere

242 S Dean St
ENGLEWOOD, NJ 07631
Registration Number: 2244812
FEI Number*: 2244812
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
DMG America, L.L.C.
242 SOUTH DEAN ST.
Englewood, NJ US 07631
Owner/Operator Number: 2244812

Official Correspondent:
George Wolfe
242 SOUTH DEAN ST.
Englewood, NJ 07631
Phone: 201-8945500-134

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 12/11/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

1 result found for **Establishment Registration or FEI Number** : *2244812*

New Search[6]

Establishment Name	▲7 ▼8	Registration Number	Current Registration Yr
DMG America LLC[9]	NJ/USA	2244812	2023

- Agent, Tooth Bonding, Resin - Agent, Tooth Bonding, Resin[10] — Contract Manufacturer
- Applicator, Resin - Applicator, Resin - DR. I.B. BIDERMAN'S BEND IT ANY W[11] — Repackager/Relabeler
- Material, Impression - Material, Impression[12] — Repackager/Relabeler
- Alloy, Amalgam - Alloy, Amalgam[13] — Manufacturer
- Varnish, Cavity - Varnish, Cavity - Kolorz[14] — Manufacturer; Repackager/Relabeler
- Alloy, Amalgam - Alloy, Amalgam[15] — Manufacturer
- Protector, Dental - Protector, Dental - Zekrya Gingival Protector; Zekrya Gingival Protector Kit; Zekrya Large Arc; Zekrya Small Arc[16] — Repackager/Relabeler
- Amalgamator, Dental, Ac-Powered - Amalgamator, Dental, AC-Powered - Zenith[17] — Manufacturer
- Agent, Polishing, Abrasive, Oral Cavity - Agent, Polishing, Abrasive, Oral Cavity - Kolorz[18] — Manufacturer; Repackager/Relabeler
- Post, Root Canal - Post, Root Canal - SPIRAPOST PFS; Spirapost PFS Introductory Package; Spirapost-Parallel Posts; Spirapost-Tapered Posts[19] — Repackager/Relabeler
- Syringe, Restorative And Impression Material - Syringe, Restorative And Impression Material - DMG Composite Dispenser[20] — Repackager/Relabeler
- Alloy, Amalgam - Alloy, Amalgam[21] — Manufacturer
- Post, Root Canal - Spirapost PFS Parallel Refill Package (10 Parallel Posts, 1 #5 Gates Glidden)[22] — Repackager/Relabeler
- Crown And Bridge, Temporary, Resin - Temp Tabs[23] — Repackager/Relabeler

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Page Last Updated: 09/18/2023

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U.S. Department of **Health & Human Services**

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DMG America, LLC
242 South Dean Street
Englewood. NJ 07631
22-3841256

Section 9:

Officer List:

Officer Name	Officer Title(s)
George Wolfe	President and COO
Patrick Crawford	Vice President of Finance
Wolfgang Muhlbauer	CEO

List of all corporation shareholders and their percent ownership:
**This is an LLC, therefore the list of members with ownership percentage is indicated.

Member Name	Percent Ownership
Alpha Dentalhandelsgesellschaft MBH & Co KG	100%

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

DMG AMERICA, LLC
0600341200

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on March 18, 2009.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 29th day of August, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6146085516

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0748824

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

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

Registered as: [X] manufacturer [X] wholesaler which conducts business at the following locations in this State:

242 SO DEAN ST ENGLEWOOD, NJ 07631-

Reg. No. 5002518

DMG AMERICA, LLC
242 SO DEAN ST
ENGLEWOOD, NJ 07631-

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

EXPIRES: January 31, 2024

Establishment Copy

07

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

Information recorded in the system as of 12/5/2023

Registration Number: 5002518 **Registered as:** Manufacturer and Wholesale
Name: DMG AMERICA, LLC
DBA:
Address: 242 SO DEAN ST, ENGLEWOOD, NJ 07631
Original Issue Date: 01/21/2000 **Expiration Date:** 01/31/2025
Current Issue Date: 10/26/2023
Disciplines: No

DMG America, LLC
242 South Dean Street
Englewood. NJ 07631

Current Permit List:

State	Permit Number	Issued Date	Expiration Date
New Jersey	5002518	1/21/2000	1/31/2025
Florida	261478	5/06/2013	5/31/2025

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/27/2023

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

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

PRODUCER
MARSH USA, LLC.
9830 Colonnade Blvd, Suite 410
San Antonio, TX 78230
Attn: ROW.CertRequest@marsh.com

CN932294392-STND-G-23-24

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Chubb Insurance Company of New Jersey	
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
DMG America LLC
65 Challenger Road, Suite 340
Ridgefield Park, NJ 07660

COVERAGES **CERTIFICATE NUMBER:** HOU-003985759-02 **REVISION NUMBER:** 1

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			9951-0677	01/01/2023	01/01/2024	EACH OCCURRENCE	$ 3,000,000
	X CLAIMS-MADE ☐ OCCUR			Retro Date: 1/01/2020			DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 3,000,000
							MED EXP (Any one person)	$ 50,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	DED ☐ RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE ☐ OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

CERTIFICATE HOLDER

DMG America LLC
65 Challenger Road, Suite 340
Ridgefield Park, NJ 07660

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285068034

Application/License No. _____

DMG America LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 242 South Dean Street, Englewood NJ, 07631 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley St., Boston, MA 02117 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 13, 2023 (Effective Date).

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

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 17th day of November, 2023.

DMG America, LLC

Authorized Representative

Liberty Mutual Insurance Company

Surety Company's Representative

Timothy Bowen, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

SIGNED and SEALED in the presence of:

see attached jurat
Witness

CELIA BASILE
NOTARY PUBLIC
STATE OF NEW JERSEY
My Commission Expires Jan. 9, 2024

Countersigned by:

Nevada Resident Agent
Robin L Amstutz, NV License# 739506

STATE OF ILLINOIS

COUNTY OF COOK

On this 17 day of NOVEMBER, 2023 before me came **Timothy Bowen** who executed the preceding instrument, to me personally known, and being by me duly sworn, said that he is the therein described and authorized ATTORNEY-IN-FACT of LIBERTY MUTUAL INSURANCE COMPANY that the seal affixed to said instrument is the Corporate Seal of said Company.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal this day and year first written above.

OFFICIAL SEAL
ROBIN L AMSTUTZ
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 10/22/2024

Robin L. Amstutz Notary Public

(Seal)

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8205092-969235**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Robin L. Amstutz, Timothy Bowen, Triniy Garcia

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 24th day of March, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 24th day of March, 2021 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 17th day of November, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: DMG America, LLC MDEG License # (if applicable): _____

Physical Address: 242 South Dean Street

City: Englewood State: NJ Zip: 07631

Mailing Address (if different from physical address): Same as physical.

City: _____ State: _____ Zip: _____

Telephone: 201-894-5505 Website: www.dmg-america.com

Licensing Company Email: dmorris@dmg-america.com

Section 2: Personal Information

First: Donna Middle: _____ Last: Morris

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

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

Mailing Address: 242 South Dean Street

City: Englewood State: NJ Zip: 07631

Telephone: 201-894-5505 x129 Email: dmorris@dmg-america.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Smithtown High School East		Graduated 1978	
Address	City	State	Zip
10 School St	St James	NY	11780
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Suffolk Community College		Attended	
Address	City	State	Zip
533 College Rd	Selden	NY	11784
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Grumman Data Sys Institute		Graduated 1983	
Address	City	State	Zip
	Woodbury	NY	
Diploma/Degree obtained, if any			
Graduated			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10-2021 to present	[redacted]	Mahwah	NJ	07430
From - To (MM/YY – MM/YY)		City	State	Zip
10-2016 to 10-202		Mahwah	NJ	07430
From - To (MM/YY – MM/YY)		City	State	Zip
08-2013 to 10-2016		Montvale	NJ	07645
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
DMG America, LLC			5/16/2011 - to Present
Business Address	**City**	**State**	**Zip**
242 South Dean Street	Englewood	NJ	07631
Phone	**Title**		**Number of Employed Hours**
201-894-5505 x129	Director of Warehouse and Manufacturing Operations		2020-2023: 7560 Hours
Description of Duties			
Effectively carry out a wide range of tasks while maintaining working teams in warehousing, pick/pack, shipping and production departments. Ensure all aspects of Company's regulatory affairs are properly maintained and adhere to the rul			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Donna Morris, **certify that as the MDEG Administrator for**

DMG America, LLC,

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

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

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

Donna Morris
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/13/2023
Date

Board Use Only	Date Received: 12/7/23

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: DMG America, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 242 South Dean Street

City: Englewood State: NJ Zip: 07631

Mailing Address (if different from physical address): Same as physical.

City: State: Zip:

Telephone: 201-894-5505 Website: www.dmg-america.com

Licensing Company Email: dmorris@dmg-america.com

Section 2: Personal Information

First: Donna Middle: Last: Morris

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

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

Mailing Address: 242 South Dean Street

City: Englewood State: NJ Zip: 07631

Telephone: 201-894-5505 x129 Email: dmorris@dmg-america.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Smithtown High School East		Graduated 1978	
Address	**City**	**State**	**Zip**
10 School St	St James	NY	11780
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Suffolk Community College		Attended	
Address	**City**	**State**	**Zip**
533 College Rd	Selden	NY	11784
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Grumman Data Sys Institute		Graduated 1983	
Address	**City**	**State**	**Zip**
	Woodbury	NY	
Diploma/Degree obtained, if any			
Graduated			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10-2021 to present	[redacted]	Mahwah	NJ	07430
10-2016 to 10-2021		Mahwah	NJ	07430
08-2013 to 10-2016		Montvale	NJ	07645
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
DMG America, LLC			5/16/2011 - to Present
Business Address	**City**	**State**	**Zip**
242 South Dean Street	Englewood	NJ	07631
Phone	**Title**		**Number of Employed Hours**
201-894-5505 x129	Director of Warehouse and Manufacturing Operations		2020-2023: 7560 Hours
Description of Duties			
Effectively carry out a wide range of tasks while maintaining working teams in warehousing, pick/pack, shipping and production departments. Ensure all aspects of Company's regulatory affairs are properly maintained and adhere to the rules and regulations set by the regulatory agencies.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Donna Morris, **certify that as the designated representative for**

DMG America, LLC,

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

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

Donna Morris

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 9/14/23

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

Donna Morris

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/14/23

Date

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

State of New Jersey, ss. County of Bergen

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

Original Signature

9/14/23

Date

Subscribed and Sworn to before me this 14th day of September, 2023.

Notary Public Signature

CELIA BASILE
NOTARY PUBLIC
STATE OF NEW JERSEY
My Commission Expires Jan. 9, 2024

(Seal)

Maria Herrera

From: Strait, Ashley L. <Ashley.Strait@quarles.com>
Sent: Thursday, January 4, 2024 9:17 AM
To: Maria Herrera
Cc: dmorris@dmg-america.com
Subject: RE: Nevada Out-of-State Wholesaler Application-DMG America, LLC [QBLLP-ACTIVE.FID42771723]

Follow Up Flag: Flag for follow up
Flag Status: Completed

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

Hi Maria,

I hope you had a wonderful holiday. We are following up in regard to the pending application for DMG America, LLC. Below, please find the information requested:

1. **A copy of the full list of employees in the facility Pursuant to NRS 639.500 (2).**

   Russell Johnson
   Ara Kochakian
   Jason DelGado
   Joel Schorr
   Calvin Glover
   Guillermo Garcia
   James Brown
   Leslie Chen
   Emma Bustos
   Martha Villacis
   Lady Salazar Garces
   John Sykes
   Albert Masbang

Thank you,

DMG America LLC
State Licensing
Nevada

Holder of Indebtedness of Application

Title	Name	Address	Phone No
Designated Representative	Donna Morris	[redacted]	201-894-5505 x129
Supervisor of Designated Representative	Patrick Crawford		201-894-5505 x317
COO and President	George Wolfe		201-894-5505 x134

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PUBLIC HEALTH AND FOOD PROTECTION PROGRAM
P.O. BOX 369, TRENTON, NJ 08625-0369
609-826-4935

REPORT OF INSPECTION

Assignment No **13702**
Inspection End Date **02/20/2020**

Registration #	Category	Inspection Type	Evaluation
5002518	**Wholesale Drug/Medical Device**	**Routine**	**Satisfactory**

Name of Owner or Corporation	Trade Name	Activity
DMG America LLC	**DMG America LLC**	**Wholesaler/Warehouse**

Establishment Street Address	City	ZIP	County
242 S Dean Street	**Englewood**	**07631**	**Bergen**

Establishment Mailing Address (if different)	Phone Number	Fax Number
	(201) 894-5505	

Name and Title of Inspecting Official	REHS Lic. #	Operational Status	Embargo	Reinspect on or After
Kate Lebedinsky, REHI	**B156230**	**Operational**	------	

Name and Title of Designated Representative	Email
Kevin Gamarello, Director of Quality and Regulatory Affairs	**kgamarello@dmg-america.com**

Products
☒ Prescription Drugs ☒ OTC Drugs ☒ Class I Medical Devices ☒ Class II Medical Devices ☐ Class III Medical Devices
☐ API ☐ Veterinary Drugs ☐ No Products Stored/Handled Onsite

TIME/ACTIVITY REPORT (1-TRAVEL, 2-INSPECTION, 3-ADMINISTRATION, 4-PERSONAL) TOTAL HOURS: 04.00

DATE	CODE	BEGIN	END	CODE	BEGIN	END	CODE	BEGIN	END
02/20/2020	1	11:30	11:45	2	11:45	14:00	1	14:00	15:00
02/21/2020	3	13:00	13:30						

		YES	NO	N/A
	N.J.A.C. 8:21-3A.7 Personnel Requirements			
	Personnel employed by a wholesale distributor have appropriate education and/or experience to assume responsibility for positions related to compliance with State registration requirements	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.8 Facility *Facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed:*			
(a) 1	Of suitable size and construction to facilitate cleaning, maintenance, and proper operations	☒	☐	☐
(a) 2	Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions	☒	☐	☐
(a) 3	Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened	☒	☐	☐
(a) 4	Maintained in a clean and orderly condition	☒	☐	☐
(a) 5	Free from infestation by insects, rodents, birds, or vermin of any kind	☒	☐	☐
Note				

		YES	NO	N/A
	N.J.A.C. 8:21-3A.9 Security			
(a)	Facility is secured from unauthorized entry	☒	☐	☐
(a) 1	Access from outside premises is kept to a minimum and is well controlled	☒	☐	☐
(a) 2	The outside perimeter of the premises is well-lighted	☒	☐	☐
(a) 3	Entry into areas where drugs are held shall be limited to authorized personnel	☒	☐	☐
(b)	All facilities are equipped with an alarm system to detect entry after hours	☒	☐	☐
(c)	Facilities are equipped with a security system that provides suitable protection against theft and diversion. When applicable, the security system provides protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.10 Storage			
(a)	All drugs are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, of the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).	☒	☐	☐
(b)	If no storage requirements are established for a drug, the drug is held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected	☒	☐	☐
(c)	Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs are utilized to document proper storage of drugs	☒	☐	☐
(d)	For prescription drugs a record is maintained that includes the date, time, thermometer temperature, and the initials of the person recording the data	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.11 Examination of Materials			
(a)	Upon receipt, each outside shipping container is visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination is adequate to reveal container damage that would suggest possible contamination or other damage to the contents.	☒	☐	☐

		YES	NO	N/A
(b)	Each outgoing shipment is carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.12 Returned, Damaged and Outdated Drugs			
(a)	Outdated, damaged, deteriorated, misbranded, or adulterated drugs are quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier	☒	☐	☐
(b)	Drugs whose immediate or sealed outer or sealed secondary containers have been opened or used are identified as such, quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier	☒	☐	☐
(c)	If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.13 Recordkeeping			
(a)	Inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs are maintained	☒	☐	☐
(a) 1	Source of drugs, name and principal address of the seller or transferor, and address from which drugs were shipped are maintained	☒	☐	☐
(a) 2-3	Identity and quantity of drugs received and distributed/disposed, date of receipt and distribution, disposal.	☒	☐	☐
(a) 5	A complete and accurate annual record of all stock of drugs on hand.	☒	☐	☐
(d)	An ongoing listing of all retail and wholesale establishments with whom they do business.	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.14 Due Diligence *Firm is performing due diligence of other wholesale establishments with whom they do business, which requires that prior to the initial purchase or acquisition of drugs from another wholesale distributor, a wholesale distributor shall obtain the following information from the selling wholesale distributor:*			
(a) 1	Copies of all state and Federal regulatory licenses and registrations	☐	☐	☒
(a) 2	The wholesale distributor's most recent facility inspection reports	☐	☐	☒
(a) 3	A list of other names under which the wholesale distributor is doing business or by which the wholesale distributor was formerly known	☐	☐	☒

		YES	NO	N/A
(a) 4	A list of corporate officers and managerial employees and designated representatives	☐	☐	☒
(a) 5	A verification of the selling wholesale distributor's status as an authorized distributor of record, if applicable.	☐	☐	☒
(b)	At least annually, a wholesale distributor that purchases prescription drugs from another wholesale distributor updates the information set forth in (a) 1-5 above.	☐	☐	☒
(c)	No purchases were placed from any storage facility, manufacturer or wholesale distributor not having a current license or registration within the jurisdiction of the establishment location from where product is purchased.	☐	☐	☒
(d)	No purchase or acquisition has been made from a firm that has not provided complete information as set forth in (a) 1-5 above.	☐	☐	☒
Note				
	N.J.A.C. 8:21-3A.15 Availability of Records and Inventories			
(a)	Records and inventories, including those related to salvage and reprocessing, are made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years after the date of their creation	☒	☐	☐
(b)	Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means are readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable are made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.16 Policies and Procedures			
(a)	Firm established and follows written policies and procedures for the receipt, security, storage, inventory, and distribution of drugs	☒	☐	☐
(a)	Firm has policies for identifying, recording and reporting losses or thefts and correcting errors in inventories	☐	☒	☐
(a) 1	Firm has a procedure where oldest stock is distributed first.	☒	☐	☐
(a) 2	Firm has a procedure for handling recalls/withdrawals of drugs.	☒	☐	☐
(a) 3	Firm has a procedure for preparation, protection and proper handling of any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster	☒	☐	☐
(a) 4	Firm has a procedure for handling return of outdated drugs; segregation and written documentation of disposal, by either returning the drug to the manufacturer or destruction of the drug. This documentation shall be maintained for 2 years after disposition of the outdated drugs.	☐	☒	☐

NEW JERSEY REPORT OF INSPECTION

		YES	NO	N/A
Note	No written procedure was established for control of and ensuring the accuracy of inventory. No written procedure was established for return to manufacturer or proper disposal of outdated products, including maintaining written documentation of the disposal. Emergency preparedness/Disaster recovery procedure did not address handling and recovery of inventory in the event of an emergency such as a natural disaster.			
	N.J.A.C. 8:21-3A.17 List of Responsible Persons			
	A current list of officers, directors, managers, and other personnel in charge of wholesale distribution, storage, and handling of prescription drugs is maintained at the firm	☒	☐	☐
	Description of duties and qualifications of personnel is maintained at the firm	☒	☐	☐
Note				
	N.J.A.C. 8:21-3A.19 Salvage; Reprocessing			
	Salvaging and reprocessing operation is in compliance with 21 CFR 207, 210, 211	☐	☐	☒
Note				

Inspecting Official

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Section 1: General Information

Facility Name: Embody Inc.

Physical Address: 4111 Monarch Way, Suite 408

City: Norfolk State: VA Zip: 23508

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.embody-inc.com

Name of Designated Representative (DR): Steve South

Licensing Company Email: EMB@slsny.com DR Email: Steven.south@zimmerbiomet.com

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

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

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

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/2022		NV		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-223	NV Board of Pharmacy

Reason/Charge
Cease and Desist

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

Name of Business/Industry/Entity
Zimmer US, Inc.

Provide explanation below:

"Yes, Zimmer US, Inc. received a Cease and Desist notice from Nevada in 2022 for selling into Nevada without the requisite license. After paying 2 fines, completing the application process, and attending a hearing before the Board of Pharmacy we were granted a Nevada license. Please see attached. If you need additional detail please let know."

Steven South — Steven Lee South
Original Signature (electronic, copies or stamps not accepted)

1/24/2024
Date

STATE LICENSE SERVICING, INC
1751 State Route 17A, Suite 3
Florida, NY 10921
Tel. 845/544-2482
Fax. 845/544-2481
statelicenseservicing.com

November 30, 2023

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

Re: **Notice of Non-Disciplinary Civil Penalty**

Embody, Inc.
4211 Monarch Way, Suite 501
Norfolk, VA 23508

License/Permit No. Pending: **Wholesaler**
4211 Monarch Way, Suite 501
Norfolk, VA 23508

Dear Licensing Authority:

This letter shall serve as disclosure of a Notice of Non-Disciplinary Civil Penalty for the above-referenced company. Embody, Inc. received a notice dated 11/03/23 from the State of Arizona State Board of Pharmacy under Case # 23-0607 for failure to disclose, in a timely manner as deemed by the Arizona Board, a change of address before the business was relocated and failure to provide notice before there was a change of ownership. A civil penalty of $750.00 was issued. The board granted Embody, Inc. 90 days from the time of issuance to pay the fine, payment was mailed to the board on 11/21/23. Now paid, the Arizona Board of Pharmacy considers the matter closed. Please see attached copy of the non-disciplinary civil penalty notice.

If you need any additional information, please feel free to email me at the address below.

Kind regards,

Jennifer Schneider
VP, Client Services
State License Servicing, Inc.
EMB@SLSNY.COM

Arizona State Board of Pharmacy
P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
https://pharmacy.az.gov/

November 3, 2023

Embody, Inc.
4211 MONARCH WAY SUITE 501
NORFOLK, VA 23508

Re: Board Case No. 23-0607

Dear Applicant,

At its meeting of October 18, 2023, the Arizona State Board of Pharmacy ("Board") reviewed your permit application. After review, the Board voted to approve your application contingent on your payment of a non-disciplinary civil penalty. Please review the enclosed Order for Non-Disciplinary Civil Penalty ("Order") carefully, as it includes the amount due and the time allowed to pay the penalty. Your permit will not be issued until the penalty is paid. If you fail to pay the civil penalty in the time allowed, your permit application will be denied.

To pay your penalty, send a check or money order for the appropriate amount to the above mailing address. Please make your check or money order payable to the Arizona State Board of Pharmacy. To ensure that you receive credit for your payment, please ensure that your name and case number are listed on your check or money order.

This Order may be subject to appeal within 35 days of the issuance of the Order under the Board's Statutes and rule. If you wish to appeal the Order, you must submit a written request to appear before the Board at a public meeting. The Board meeting schedule is available on the Board's website.

If you have any questions regarding this notice, please contact Jennifer Mitchell, Executive Staff Assistant at (602) 771-2761 or jmitchell@azpharmacy.gov.

Sincerely,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

Enclosure

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington, Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
Phone: 602-771-2727 Fax: 602-771-2749 pharmacy.az.gov

Order for Non-Disciplinary Civil Penalty

In the Matter of:

Respondent Name	Embody, Inc.
License/Permit No.	M002253 (Applicant)
Board Case No.	23-0607

	Check all that apply:			Fine(s)
☐	Failing to submit a remodel application before remodeling a permitted facility.			$250
☒	Failing to provide notice before a business is relocated.			$500
☐	Failing to update contact information within 10 days.			$50
☐	Failing to update change of employment information within 10 days.			$50
☐	Failing to complete required continuing education for pharmacist. (First offense)	Deficient CEs:		$100/CE
☐	Failing to complete required continuing education for pharmacist. (Second offense)	Deficient CEs:		$150/CE
☐	Failing to complete required continuing education for technician. (First offense)	Deficient CEs:		$25/CE
☐	Failing to complete required continuing education for technician. (Second offense)	Deficient CEs:		$37.50/CE
☐	Failing to provide notice of a new pharmacist in charge within 14 days.			$100
☐	Failing to provide notice of a new designated representative within 10 days.			$100
☐	Failing to provide notice of a new criminal charge, arrest, or conviction in any jurisdiction.			$250
☐	Failing to provide notice of disciplinary action taken against the licensee or permittee in any jurisdiction.			$250
☐	Failing to renew a pharmacist license timely within 60 days and continuing to work with an expired license.*	Days worked:		$100/day
☐	Failing to renew a technician license timely within 60 days and continuing to work with an expired license. **	Days worked:		$50/day
☐	Failing to conduct a controlled substance inventory when there is a new pharmacist in charge within 10 days.			$250
☐	Failing to obtain a permit before shipping into Arizona anything for which a permit is required.	Items:		$100/Item
☐	Failing to respond timely to a subpoena.			$50
☒	Failing to provide notice before there is a change in ownership.			$250
☐	Failing to conduct required controlled substance inventories.			$250
☐	Failing to provide written notice to the Board at least 14 days before discontinuing operation of the pharmacy.			$250
☐				
			TOTAL:	$750
*Max $1,000				
**Max $500				
For Office Use Only				
Comment:				

The non-disciplinary civil penalty shall be paid within 90 days from the date of issuance of this order. Failure to pay the non-disciplinary civil penalty within 90 days from date of issuance of this order shall result in this case being presented to the Board and may be subject to disciplinary action. If the licensee/permittee wishes to request a rehearing/review of the Order, the request shall be filed within 35 days of the issuance of the Order under the Board's Statutes and rule.

Payment can be made using check or money order to: Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Executive Director's Signature: Kam Gandhi

Issue Date: November 3, 2023

Silicon Valley Bank
90-1039/1211

1952

Embody Inc
4211 Monarch Way, Suite 500
Norfolk, VA 23508

11/21/2023

PAY TO THE ORDER OF Arizona State Board of Pharmacy $ 750.00

Seven hundred fifty dollars & 00/100 DOLLARS

MEMO State Licensing Penalty
Case # 23-0607

AUTHORIZED SIGNATURE

Photo Safe Deposit®

Details on Back.

1952

1952

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS, AND PROFESSIONAL LICENSING
Anchorage Office

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Toll free fax: 907.269.8156

CERTIFIED# 7019 2970 0001 2072 4344
RETURN RECEIPT REQUESTED

December 4, 2023

Embody, Inc.
Attn: Steven South
4211 Monarch Way, Suite 500
Norfolk, VA 23508

RE: Case No. 2023-000403

Mr. South:

This letter shall serve as formal notice to you that the Alaska Board of Pharmacy, during its November 16, 2023 meeting, adopted the Imposition of Civil Fine, presented to the Board by members of the staff from the Division of Corporations, Business and Professional Licensing. A copy of the Imposition of Civil Fine and Order, as adopted, is enclosed.

If you wish to pay with a credit card, a payment form has been included for your convenience.

Please be advised that you were under official investigation by the Alaska Board and this subsequent disciplinary action is a public record. You may be required to report this license action and to disclose it when applying for licensure in other states. Should you have any questions regarding this matter, please do not hesitate to contact me at the address and telephone number listed above.

Sincerely,

DocuSigned by:
Erika Pricksat
34F98CE5F1DF46C...
Erika Pricksat,
Chief Investigator

cc: Sylvan Robb, Director CBPL
Glenn Saviers, CBPL Deputy Director
Michael Bowles, Executive Administrator
Holly Handley, Investigator
Marilyn Zimmerman, Paralegal II
Julienne Kim, Paralegal II
Litigation File 2023-000403 (Original)

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2023-000403

I, Steven South, as an agent for Embody, Inc., admit and agree the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of Out-of-State Wholesale Drug Distributor License No. 186958, and over this Imposition of Civil Fine.

1. On February 14, 2023, we appointed a new Facility Manager in reference to License #186958.
2. On April 11, 2023, we submitted our Change of Facility Manager/ Pharmacist-in-Charge form with the new Facility Manager notification to the Board; 56 days after the Facility Manager change occurred.
3. This is a violation of 12 AAC 52.635(a).

We admit that as a result of these facts, grounds exist for possible denial of licensure or other disciplinary sanctions of my license pursuant to AS 08.01.75 and 12 AAC 52.635(a). We are agreeing to this Imposition of a Civil Fine of three hundred dollars ($300) in cash, certified check, or money order payable to the "**State of Alaska**" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board.

We have the right to consult with an attorney, and a right to an administrative hearing on the facts in this case. We understand and agree by voluntarily signing this Imposition of Civil Fine, we are waiving our rights to counsel and to a hearing on this matter.

Steven South
Agent for Embody, Inc. (Signature)

8/9/2023
Date

SUBSCRIBED AND SWORN TO before me this 9th day of August, 2023, at 4211 Monarch Way, VA (state).

SEAL

Patrice Nicole Gooden
Notary Public in and for VA (state)

BH
BH

PATRICE NICOLE GOODEN
NOTARY PUBLIC
REG. # 7983282
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES OCTOBER 31, 2026

Patrice Nicole Gooden
Notary Printed Name
My commission expires: 10/31/2026

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

In the Matter of:)
)
Embody, Inc.)
)
Respondent)
Case No. 2023-000403

ORDER

The Alaska Board of Pharmacy (Board), having examined the Imposition of Civil Fine, Case No. 2023-000403, regarding License No. #186958, for failure to timely notify the Board of a Facility Manager change, hereby adopts the Imposition of Civil Fine.

The Board has determined this is a technical violation of professional licensing statutes and regulations, therefore this matter can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 16th day of November, 2023, at Anchorage, Alaska.

ALASKA BOARD OF PHARMACY

By: Ashley Schaber
Board Chair

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

THE STATE of ALASKA
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing

FOR DIVISION USE ONLY

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West. 7th Avenue. Suite 1500, Anchorage, AK 99501-3567
Phone: (907) 269-8124

Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: _____

Program Type: _____ License Number *(if applicable)*: _____

I wish to make payment by credit card for the following *(check all that apply)*: **AMOUNT**

- ☐ Application Fee: _____ _____
- ☐ License or Renewal Fee: _____ _____
- ☐ Other *(name change, wall certificate, fine, duplicate license, exam, etc.)*:
  1. _____ _____
  2. _____ _____

TOTAL: _____

Name *(as shown on credit card)*: _____

Mailing Address: _____

Phone Number: _____ Email *(optional)*: _____

Signature of Credit Card Holder: _____ _____

08-4438 Rev 12/26/18 Credit Card Payment Form (all major cards accepted)

CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!

1. Account Number: _____
2. Expiration Date: _____
3. Billing ZIP Code: _____
4. Security Code: _____

All four fields **MUST** be completed!

This section will be destroyed after the payment is processed.

0364

Embody Inc
4211 Monarch Way, Suite 500
Norfolk, VA 23508

Silicon Valley Bank
90-4039/1211

1953

12/21/2023

PAY TO THE ORDER OF State of Alaska $300.00

Three hundred dollars & no/100 DOLLARS

MEMO Civil Fine; Case # 2023-000403

[redacted]

AUTHORIZED SIGNATURE

⑈001953⑈ [redacted]

Photo Safe Deposit®

Details on Back.

1953

1953

Joe Dodge

From: Pharmacy Board
Sent: Tuesday, December 5, 2023 7:21 AM
To: Joe Dodge
Cc: David Wuest
Subject: Fw: Embody, Inc. - Notice of Non-Disciplinary Civil Penalty
Attachments: EMB-XVA-AZ-Case #23-0607-Payment_Redacted.pdf

Thank you.

MP03011

Nevada State
Board of Pharmacy
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
Office: 775-850-1440
Fax: 775-850-1444
Web Page: https://bop.nv.gov/

From: compliance@slsnysupport.com <compliance@slsnysupport.com>
Sent: Thursday, November 30, 2023 10:21 AM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>
Subject: Embody, Inc. - Notice of Non-Disciplinary Civil Penalty

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

IMPORTANT NOTICE

State License Servicing, Inc.
1751 State Route 17A, Suite 3, Florida, NY 10921
(845) 544-2482 Office, (845) 544-2481 Fax

Date: November 30, 2023
To: Nevada State Board of Pharmacy
Re: Embody, Inc., 4211 Monarch Way, Suite 501, Norfolk, VA 23508, Permit #: Pending - Initial

Dear Licensing Authority:

This letter shall serve as disclosure of a Notice of Non-Disciplinary Civil Penalty for the above-referenced company. Embody, Inc. received a notice dated 11/03/23 from the State of Arizona State Board of Pharmacy under Case # 23-0607 for failure to disclose, in a timely manner as deemed by the Arizona Board, a change of address before the business was relocated and failure to provide notice before there was a change of ownership. A civil penalty of $750.00 was issued. The board granted Embody, Inc. 90 days from the time of issuance to pay the fine, payment was mailed to the board on 11/21/23. Now paid, the Arizona Board of Pharmacy considers the matter closed. Please see attached copy of the non-disciplinary civil penalty notice.

If you need any additional information, please feel free to email me at the address below.

Kind Regards,

Jennifer Schneider
V.P. Client Services
(845) 544-2482 ext 207
jennifers@slsny.com

THIS ELECTRONIC MAIL MESSAGE AND ANY ATTACHMENT IS CONFIDENTIAL AND MAY CONTAIN LEGALLY PRIVILEGED INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR INDIVIDUALS NAMED ABOVE.
If the reader is not the intended recipient or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please reply to the sender to notify us of the error and delete the original message.
Thank You

Click Here to Respond to this Email

Arizona State Board of Pharmacy
P.O. Box 18520, Phoenix, AZ 85005
P) 602-771-2727 F) 602-771-2749
https://pharmacy.az.gov/

November 3, 2023

Embody, Inc.
4211 MONARCH WAY SUITE 501
NORFOLK, VA 23508

Re: Board Case No. 23-0607

Dear Applicant,

At its meeting of October 18, 2023, the Arizona State Board of Pharmacy ("Board") reviewed your permit application. After review, the Board voted to approve your application contingent on your payment of a non-disciplinary civil penalty. Please review the enclosed Order for Non-Disciplinary Civil Penalty ("Order") carefully, as it includes the amount due and the time allowed to pay the penalty. Your permit will not be issued until the penalty is paid. If you fail to pay the civil penalty in the time allowed, your permit application will be denied.

To pay your penalty, send a check or money order for the appropriate amount to the above mailing address. Please make your check or money order payable to the Arizona State Board of Pharmacy. To ensure that you receive credit for your payment, please ensure that your name and case number are listed on your check or money order.

This Order may be subject to appeal within 35 days of the issuance of the Order under the Board's Statutes and rule. If you wish to appeal the Order, you must submit a written request to appear before the Board at a public meeting. The Board meeting schedule is available on the Board's website.

If you have any questions regarding this notice, please contact Jennifer Mitchell, Executive Staff Assistant at (602) 771-2761 or jmitchell@azpharmacy.gov.

Sincerely,

Kam Gandhi

Kam Gandhi, PharmD
Executive Director

KG/jcm

Enclosure

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington, Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
Phone: 602-771-2727 Fax: 602-771-2749 pharmacy.az.gov

Order for Non-Disciplinary Civil Penalty

In the Matter of:

Respondent Name	Embody, Inc.
License/Permit No.	M002253 (Applicant)
Board Case No.	23-0607

	Check all that apply:			Fine(s)
☐	Failing to submit a remodel application before remodeling a permitted facility.			$250
☒	Failing to provide notice before a business is relocated.			$500
☐	Failing to update contact information within 10 days.			$50
☐	Failing to update change of employment information within 10 days.			$50
☐	Failing to complete required continuing education for pharmacist. (First offense)	Deficient CEs:		$100/CE
☐	Failing to complete required continuing education for pharmacist. (Second offense)	Deficient CEs:		$150/CE
☐	Failing to complete required continuing education for technician. (First offense)	Deficient CEs:		$25/CE
☐	Failing to complete required continuing education for technician. (Second offense)	Deficient CEs:		$37.50/CE
☐	Failing to provide notice of a new pharmacist in charge within 14 days.			$100
☐	Failing to provide notice of a new designated representative within 10 days.			$100
☐	Failing to provide notice of a new criminal charge, arrest, or conviction in any jurisdiction.			$250
☐	Failing to provide notice of disciplinary action taken against the licensee or permittee in any jurisdiction.			$250
☐	Failing to renew a pharmacist license timely within 60 days and continuing to work with an expired license.*	Days worked:		$100/day
☐	Failing to renew a technician license timely within 60 days and continuing to work with an expired license. **	Days worked:		$50/day
☐	Failing to conduct a controlled substance inventory when there is a new pharmacist in charge within 10 days.			$250
☐	Failing to obtain a permit before shipping into Arizona anything for which a permit is required.	Items:		$100/Item
☐	Failing to respond timely to a subpoena.			$50
☒	Failing to provide notice before there is a change in ownership.			$250
☐	Failing to conduct required controlled substance inventories.			$250
☐	Failing to provide written notice to the Board at least 14 days before discontinuing operation of the pharmacy.			$250
☐				
			TOTAL:	$750
*Max $1,000				
**Max $500				
For Office Use Only				
Comment:				

The non-disciplinary civil penalty shall be paid within 90 days from the date of issuance of this order. Failure to pay the non-disciplinary civil penalty within 90 days from date of issuance of this order shall result in this case being presented to the Board and may be subject to disciplinary action. If the licensee/permittee wishes to request a rehearing/review of the Order, the request shall be filed within 35 days of the issuance of the Order under the Board's Statutes and rule.

Payment can be made using check or money order to: Arizona State Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005

Executive Director's Signature: Kam Gaddis

Issue Date: November 3, 2023

Embody Inc
4211 Monarch Way, Suite 500
Norfolk, VA 23508

Silicon Valley Bank
90-1039/1211

1952

11/21/2023

PAY TO THE ORDER OF Arizona State Board of Pharmacy $ 750.00 —

Seven hundred fifty dollars & no/100 DOLLARS

Photo Safe Deposit®

Details on Back.

MEMO State Licensing Penalty
Case# 23-0607

AUTHORIZED SIGNATURE

1952

1952

12/18/23

OOS Disclosure Adjudication

Licensee:	Embody Inc
License #:	MP03011
Date of notification:	11/30/23
NVBOP employee:	Joe Dodge

$750 fine from Arizona BOP for failure to timely report change of address and change of ownership.

NVBOP takes no further action at this time

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

Name: _____

Address: Attached City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: VA

Parent Company (if any): Zimmer Biomet Holdings, Inc. - 100 %

Corporation Name: Embody, Inc.

Mailing Address: c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Email: EMB@slsny.com

Contact Person Name: Christine Cannon

Date of SEC Registration: 08/06/2001 | SEC Registration Number: CIK: 0001136869 | Stock Exchange Symbol: ZBH

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

Name: ATC Technologies, Inc
Address: 30-B Upton Drive City: Wilmington State: MA Zip: 01887
Name: Confluent Medical Technologies
Address: 6263 N. Scottsdale Road, Ste. 224 City: Scottsdale State: AZ Zip: 85250
Name: Crescent Industries, Inc
Address: 70 E. High Street City: New Freedom State: PA Zip: 17349
Name: Collagen Solutions
Address: 6575 City West Parkway City: Eden Prairie State: MN Zip: 55334

Section 4: Publicly Traded Corporation

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

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: VA
Parent Company (if any): Zimmer Biomet Holdings, Inc.
Corporation/Organization Name: Embody, Inc.
Mailing Address: c/o State License Servicing, 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: EMB@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

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

Section 7: Sole Owner

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

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 3015543569	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - 100% sole ownership		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Embody Inc.

Facility Name

Steven Lee South

Print Name of Authorized Person Submitting Application

Steven South

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

5/2/2023

Date

Board Use Only	Date Received: 6-5-23	Amount: 1000.00 CK-203

U.S. Department of Health & Human Services

a A A

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SEARCH

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA, U.S. Food and Drug Administration

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home · Medical Devices · Databases

New Search

Back To Search Results

Establishment:
Embody, Inc.
4211 Monarch Way
Suite 500
Norfolk, VA 23508
Registration Number: 3015543569
FEI Number*: 3015543569
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
Embody, Inc.
4211 Monarch Way
Suite 500
Norfolk, VA US 23508
Owner/Operator Number: 10079091

Official Correspondent:
Brianna Schehr
4211 Monarch Way
Suite 500
Norfolk, VA 23508
Phone: 1-236-9947912

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 04/24/2023
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

Accessibility | Contact FDA | Careers | FDA Basics | FOIA | No FEAR Act | Nondiscrimination | Website Policies / Privacy

U.S. Food and Drug Administration

Combination Products

U.S. Department of Health & Human Services

FDA Proof

Embody, Inc.

Corporate Address: 4211 Monarch Way, Suite 500, Norfolk, VA 23508 USA
FEIN: 83-3990973
www.embody-inc.com

Drug Labeler Code: UDI -
Incorporation State: VA
Incorporation Date: 12/13/2018

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
XVA	4211 Monarch Way Suite 501 Norfolk, VA 23508 County:	3015543569	N/A - No CS		No	(757) 777-5674	

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Steven Lee South	[redacted]	Finance Manager		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Zimmer Biomet Holdings, Inc.	345 East Main Street Warsaw, IN 46580	N/A	100	N/A	13-4151777	N/A	N/A

LIST OF OFFICERS

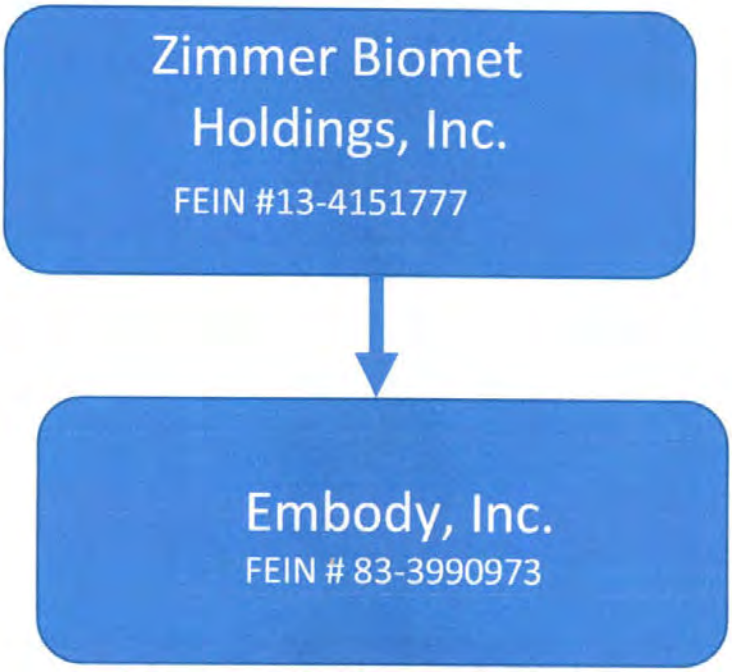
Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Steven Lee South	[redacted]	Finance Manager		[redacted]		
Matthew R. St. Louis		Vice President and Assistant Secretary				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

EMBODY

Embody, Inc. Ownership Chart



Officer List

List of Officers

Matthew R. St. Louis - Vice President & Assistant Secretary
Steven Lee South - Finance Manager

Steven Lee South

Home State (VA)
+ Incorp Good Standing

0379

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That Embody, Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on December 13, 2018;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

May 3, 2023

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 2023050318711030

Home State (VA) License Verification

0380

Virginia Department of Health Professions
License Lookup

Current as of 05/04/2023 09:59

License Information

License Number	0216000183
Occupation	Warehouser
Name	Embody, Inc
Address	4211 Monarch Way, Suite 501 Norfolk, VA 23508
Initial License Date	10/22/2020
Expire Date	02/29/2024
License Status	Current Active
Additional Public Information*	No

Back to License Lookup Result

This serves as primary source verification of the credential issued by the Commonwealth of Virginia and meets the requirements of the Joint Commission.

* *"Yes" means that there is information the Department must make available to the public pursuant to §54.1-2400.2.H of the Code of Virginia; please note that this may also include proceedings in which a finding of "no violation" was made. For additional information click on the "Yes" link above. "No" means no documents are available.*

Back to License Lookup

Home State (VA) No official VOL

0381

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527 4475

August 25, 2020

Stephen Schneider
State License Servicing Inc
1751 State Route 17A Suite 3
Florida NY 10921

Our agency has received a payment for **Non-restricted Manufacturer** verification of licensure application fee. The payment and/or accompanying documentation is being returned to you for the following reason(s)

- ☐ Payment is not owed to this agency.
- ☐ Our agency does not charge a fee for the requested service.
- ☐ There is insufficient information to process the payment.
- ☐ Signer of the check does not match preprinted checking account owner.
- ☐ Legal or written amounts do not match/not filled out.
- ☐ No signature on check.
- ☐ Payment is stale dated (over 6 months old)/post-dated.
- ☐ Application must be processed online at www.dhp.virginia.gov/
- ☐ Other: The Board of Pharmacy no longer process verifications.

Please contact the **Board of Pharmacy** at **804-367-1923** for questions regarding the reason your payment was returned and all licensure questions.

License # 0208008203 **Applicant(#** 1223480

Prepared By: Nanette Tunstall **Approved By:**

Important Notice:
If the check and letter are returned to the Board or Support Unit undeliverable, immediately forward to Centralized Receipting Center of the Finance Division. The Finance Division is the only department authorized to handle these undeliverable items.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/27/2023

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

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

PRODUCER
MARSH USA, LLC.
6410 Poplar Avenue, Suite 540
Memphis, TN 38119
Attn: Karen Angus (k.angus@marsh.com)

CN103092394-ZB-GAWU-23-24

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hartford Fire Insurance Co	19682
INSURER B : Hartford Accident & Indemnity Co.	22357
INSURER C : N/A	N/A
INSURER D : Twin City Fire Insurance Co	29459
INSURER E : Hartford Casualty Ins Co	29424
INSURER F : Hartford Underwriters Insurance Company	30104

INSURED
Zimmer Biomet Holdings, Inc.
Attn: Maureen Smith
345 E. Main Street
Warsaw, IN 46580

COVERAGES

CERTIFICATE NUMBER: ATL-005603084-02 **REVISION NUMBER:** 3

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			20CS31702	10/01/2023	10/01/2024	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 5,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 2,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$ 4,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ EXCLUDED
								$
A	**AUTOMOBILE LIABILITY**			20ABS31704 AOS	10/01/2023	10/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
F	X ANY AUTO			20ABS31706 HI	10/01/2023	10/01/2024	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N			20WNS31700 (AOS)	10/01/2023	10/01/2024	X PER STATUTE OTH-ER	
D	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N/A		20WBRS31701 - Retro (WI,MA)	10/01/2023	10/01/2024	E.L. EACH ACCIDENT	$ 1,000,000
E	**(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			20 XWE S31707 - Excess (OH)	10/01/2023	10/01/2024	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
				Ohio - SIR $250,000			E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Embody Acquired by Zimmer 2-14-2023

CERTIFICATE HOLDER

Embody Inc.
4211 Monarch Way Suite 501
Norfolk, VA 23508

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 11/07/2023

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

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PRODUCER
MARSH USA, LLC.
6410 Poplar Avenue, Suite 540
Memphis, TN 38119
Attn: Karen Angus (k.angus@marsh.com)

CN103092394-ZB-GAWU-23-24

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Hartford Fire Insurance Co	19682
INSURER B : Hartford Accident & Indemnity Co.	22357
INSURER C : N/A	N/A
INSURER D : Twin City Fire Insurance Co	29459
INSURER E : Hartford Casualty Ins Co	29424
INSURER F : Hartford Underwriters Insurance Company	30104

INSURED
Zimmer Biomet Holdings, Inc.
Attn: Maureen Smith
345 E. Main Street
Warsaw, IN 46580

COVERAGES **CERTIFICATE NUMBER:** ATL-005603084-03 **REVISION NUMBER:** 5

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			20CS31702	10/01/2023	10/01/2024	EACH OCCURRENCE	$ 2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ EXCLUDED
	OTHER:							$
A	AUTOMOBILE LIABILITY			20ABS31704 AOS	10/01/2023	10/01/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
F	X ANY AUTO			20ABS31706 HI	10/01/2023	10/01/2024	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			20WNS31700 (AOS)	10/01/2023	10/01/2024	X PER STATUTE OTH-ER	
D	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		20WBRS31701 - Retro (WI,MA)	10/01/2023	10/01/2024	E.L. EACH ACCIDENT	$ 1,000,000
E	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			20 XWE S31707 - Excess (OH)	10/01/2023	10/01/2024	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
				Ohio - SIR $250,000			E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Includes Embody Inc - Acquired by Zimmer Inc 2-14-2023

CERTIFICATE HOLDER

Embody Inc.
4211 Monarch Way Suite 501
Norfolk, VA 23508

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Embody, Inc. MDEG License # (if applicable) N/A

Physical Address 4211 Monarch Way, Suite 501

City Norfolk State VA Zip 23508

Mailing Address (if different from physical address) c/o State License Servicing, 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website www.embody-inc.com

Licensing Company Email EMB@SLSNY.COM

Section 2: Personal Information

First Michael Middle Noel Last Spencer

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

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

Mailing Address [redacted]

City Chesapeake State VA Zip 23323

Telephone [redacted] Email michael.spencer1@zimmerbiomet.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
New York Institue		2005-2007	
Address	**City**	**State**	**Zip**
41 E 11th St	New York	NY	10003
Diploma/Degree obtained, if any			
Photography			

School Name		From - To (MM/YY – MM/YY)	
Electronic Computer Programing Institute University		1990-1991	
Address	**City**	**State**	**Zip**
1001 Omni Blvd	Newport News	VA	23606
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Kecoughtan High School		1985-1989	
Address	**City**	**State**	**Zip**
522 Woodland Rd	Hampton	VA	23669
Diploma/Degree obtained, if any			
General			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2021 - Present	[redacted]	Chesapeake	VA	23323
From - To (MM/YY – MM/YY)		City	State	Zip
05/2009 - 06/2021		Hampton	VA	23669
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Embody, Inc.			10/2016 - Present
Business Address	**City**	**State**	**Zip**
4211 Monarch Way, Suite 501	Norfolk	VA	23508
Phone	**Title**	**Number of Employed Hours**	
(757) 536-2766	Designated Representative	~ 14,560 hrs	

Description of Duties

Oversee and coordinate daily operations. Provide a pivotal role into the smooth functioning of the production process. Work closely with system engineers and scientist on creating quality products in a timely manner to support our customer base. Ensure products are manufactured efficiently and meet the highest quality standards while motivating team members to achieve production targets while adhering to safety protocols and compliance regulations.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

N/A

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Michael Noel Spencer, certify that as the MDEG Administrator for

Embody, Inc.,

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

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

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

Michael Noel Spencer
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

23 OCT 2023
Date

Board Use Only	Date Received: _____

Last	First	Dept.	Title
Nelson	Christine	Executive	VP Manufacturing & Logistics
Schehr	Brianna	Executive	VP Quality, Regulatory & Clinical Affairs
Havener	Matt	Executive	VP Product Development
Rizzo	John	Sales	SVP Sales
Gooden	Patrice	Admin	Office Associate
Murphy	Lynne	Customer Care	Commercial Ops. Supervisor
Phillos	Vicki	Customer Care	Dir. Commercial Operations
Lahammer	Halle	Customer Care	Commercial Ops Specialist
Smith	William	Customer Care	Commercial Ops Specialist
Sirianni	Jeff	Fin. & Admin	Operations Director
South	Steven	Fin. & Admin	Finance Manager
Spencer	Michael	Manufacturing	Manufacturing Manager
Estes	Kindel	Manufacturing	Sr. Manufacturing Specialist
Huey	Ryan	Manufacturing	Inventory Specialist
Leone	Keith	Manufacturing	Manufacturing Specialist
Tinguria	Megha	Manufacturing	Manufacturing Engineer
Bridges	Tori	Manufacturing	Inventory Support
Bell	Jeffrey	Manufacturing	Production Support Specialist
Wharton	Scott	Manufacturing	Demand & Supply Planner
Roose	David	Manufacturing	Director of Manufacturing
Hamdan	Julianna	Marketing	Project Manager
Spady	Michelle	Quality	Sr. Quality Systems Manager
Pritchard	Erin	Quality	Quality Specialist
Spady	Raphawn	Quality	Quality Control Specialist
Johnson	Zabrina	Quality	SR Quality Engineer
McNally	Stephanie	Quality	Quality Control Manager
Sori	Nardos	R&D	Scientific Director, R&D
Wiggers	Hilary	R&D	Laboratory Manager
Maghdouri-White	Yas	R&D	Scientific Director, R&D
Christensen	Kyle	R&D	Sr. R&D Engineer
Dasgupta	Amrita	R&D	Sr. Scientist
Nair	Rohith	R&D	Sr. Advanced Manufacturing Engineer
Stagnaro	Victoria	R&D	Sr. Research Associate
Wills	Kyle	R&D	Dir. Program Management
Hollins (Blair)	Stacy	R&D	Sr Product Developer
Carey	Amanda	R&D	Sr. Research Associate
Howell	Andrew	R&D	R&D Scientist
McLaughlin	Aaron	Sales	Area VP Sales -Central US
Garadella	John	Sales	Director of National Accounts

Boosalis	Michael	Sales	Biologics Account Manager
Conrad	Erik	Sales	Biologics Account Manager
Yanovitch	Mike	Sales	Biologics Account Manager
Patane	John	Sales	Area VP Sales - East US
Scheib	Blake	Sales	Area Sales Manager
Lincoln	Scott	Sales	Biologics Account Manager
Axelrod	Jason	Sales	Area Sales Manager
Arnold	Andrea	Sales	Biologics Account Manager
Washychyn	Eric	Sales	Clinical/Medical Educ. Specialist
Wirth	Steven	Sales	Biologics Account Manager
Hansen	Joseph	Sales	Biologics Account Manager

NEVADA STATE BOARD OF PHARMACY

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

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 016240092

Application/License No. _____

Embody, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4211 Monarch Way, Suite 501, Norfolk, VA 23508 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02117 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 11, 2023 (Effective Date).

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

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 11th day of May, 20 23.

APPLICANT/PRINCIPAL

COMPANY
Embody, Inc.

Authorized Representative

SURETY

Liberty Mutual Insurance Company

Surety Company's Representative

Elizabeth A. Hartzberg, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Maria Concepcion

Witness Camille M. Cruz

Countersigned by:

N/A
Nevada Resident Agent

PATRICE NICOLE GOODEN
NOTARY PUBLIC
REG. # 7983282
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES OCTOBER 31, 2026

Liberty Mutual SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Elizabeth A. Hartzberg

all of the city of Pittsburgh, state of Pennsylvania each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 11th day of May, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED June 30, 2023

Commission File Number 001-16407

ZIMMER BIOMET HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4151777**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

345 East Main Street, Warsaw, IN 46580
(Address of principal executive offices)
Telephone: (574) 373-3333

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	**ZBH**	**New York Stock Exchange**
2.425% Notes due 2026	**ZBH 26**	**New York Stock Exchange**
1.164% Notes due 2027	**ZBH 27**	**New York Stock Exchange**

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

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

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

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

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

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

As of July 26, 2023, 208,964,134 shares of the registrant's $.01 par value common stock were outstanding.

ZIMMER BIOMET HOLDINGS, INC.
INDEX TO FORM 10-Q
June 30, 2023

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Part I – Financial Information

Item 1. Financial Statements

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF EARNINGS
(in millions, except per share amounts, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net Sales	$ 1,869.6	$ 1,781.8	$ 3,700.6	$ 3,445.0
Cost of products sold, excluding intangible asset amortization	525.5	511.0	1,026.3	1,011.0
Intangible asset amortization	138.2	133.0	271.6	263.8
Research and development	118.1	99.4	228.5	196.3
Selling, general and administrative	725.8	695.2	1,441.8	1,379.7
Intangible asset impairment	-	3.0	-	3.0
Restructuring and other cost reduction initiatives	24.4	57.0	66.3	100.9
Quality remediation	-	7.8	-	14.3
Acquisition, integration, divestiture and related	7.9	(5.5)	9.1	(3.3)
Operating expenses	1,539.9	1,500.9	3,043.6	2,965.7
Operating Profit	329.6	280.9	656.9	479.3
Other (expense) income, net	(1.2)	(42.6)	6.5	(98.7)
Interest expense, net	(51.6)	(38.8)	(99.8)	(79.9)
Earnings from continuing operations before income taxes	276.8	199.5	563.6	300.7
Provision for income taxes from continuing operations	66.9	45.5	121.0	73.5
Net Earnings from continuing operations	209.9	154.0	442.6	227.2
Less: Net earnings attributable to noncontrolling interest	0.2	0.3	0.5	0.5
Net Earnings from Continuing Operations of Zimmer Biomet Holdings, Inc.	209.6	153.7	442.1	226.7
Loss from discontinued operations, net of taxes	-	-	-	(58.8)
Net Earnings of Zimmer Biomet Holdings, Inc.	$ 209.6	$ 153.7	$ 442.1	$ 167.9
Earnings Per Common Share - Basic				
Earnings from continuing operations	$ 1.00	$ 0.73	$ 2.12	$ 1.08
Loss from discontinued operations	-	-	-	(0.28)
Net Earnings Per Common Share - Basic	$ 1.00	$ 0.73	$ 2.12	$ 0.80
Earnings Per Common Share - Diluted				
Earnings from continuing operations	$ 1.00	$ 0.73	$ 2.10	$ 1.08
Loss from discontinued operations	-	-	-	(0.28)
Net Earnings Per Common Share - Diluted	$ 1.00	$ 0.73	$ 2.10	$ 0.80
Weighted Average Common Shares Outstanding				
Basic	208.6	209.6	209.0	209.4
Diluted	209.9	210.3	210.1	210.2

The accompanying notes are an integral part of these condensed consolidated financial statements.

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
(in millions, unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net Earnings of Zimmer Biomet Holdings, Inc.	$ 209.6	$ 153.7	$ 442.1	$ 167.9
Other Comprehensive Income (Loss):				
Foreign currency cumulative translation adjustments, net of tax	(26.5)	(92.1)	(14.1)	(90.8)
Unrealized cash flow hedge gains, net of tax	47.1	65.6	55.9	79.3
Reclassification adjustments on hedges, net of tax	(19.3)	(9.7)	(38.3)	(14.0)
Adjustments to prior service cost and unrecognized actuarial assumptions, net of tax	(1.1)	2.6	(2.0)	3.5
Total Other Comprehensive Income (Loss)	0.2	(33.6)	1.5	(22.0)
Comprehensive Income Attributable to Zimmer Biomet Holdings, Inc.	$ 209.8	$ 120.1	$ 443.6	$ 145.9

The accompanying notes are an integral part of these condensed consolidated financial statements.

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions, except share amounts, unaudited)

	June 30, 2023	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 319.8	$ 375.7
Accounts receivable, less allowance for credit losses	1,367.3	1,381.5
Inventories	2,275.8	2,147.2
Prepaid expenses and other current assets	425.1	522.9
Total Current Assets	4,387.9	4,427.3
Property, plant and equipment, net	1,975.0	1,872.5
Goodwill	8,743.7	8,580.2
Intangible assets, net	5,027.7	5,063.8
Other assets	1,160.0	1,122.2
Total Assets	$ 21,294.3	$ 21,066.0
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 354.6	$ 354.1
Income taxes payable	81.6	38.5
Other current liabilities	1,277.6	1,421.3
Current portion of long-term debt	520.0	544.3
Total Current Liabilities	2,233.7	2,358.2
Deferred income taxes, net	474.9	474.8
Long-term income tax payable	375.7	421.2
Other long-term liabilities	642.0	632.6
Long-term debt	5,189.4	5,152.2
Total Liabilities	8,915.8	9,039.0
Commitments and Contingencies (Note 16)		
Stockholders' Equity:		
Zimmer Biomet Holdings, Inc. Stockholders' Equity:		
Common stock, $0.01 par value, one billion shares authorized, 315.8 million shares as of June 30, 2023 (313.8 million as of December 31, 2022) issued	3.2	3.1
Paid-in capital	9,766.0	9,504.4
Retained earnings	9,902.3	9,559.3
Accumulated other comprehensive loss	(177.8)	(179.3)
Treasury stock, 107.0 million shares as of June 30, 2023 (104.8 million as of December 31, 2022)	(7,122.2)	(6,867.2)
Total Zimmer Biomet Holdings, Inc. stockholders' equity	12,371.5	12,020.3
Noncontrolling interest	7.1	6.7
Total Stockholders' Equity	12,378.6	12,027.0
Total Liabilities and Stockholders' Equity	$ 21,294.3	$ 21,066.0

The accompanying notes are an integral part of these condensed consolidated financial statements.

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in millions, except per share amounts, unaudited)

	Zimmer Biomet Holdings, Inc. Stockholders								
	Common Shares		Paid-in	Retained	Accumulated Other Comprehensive (Loss) Income	Treasury Shares		Noncontrolling Interest	Total Stockholders' Equity
	Number	Amount	Capital	Earnings		Number	Amount		
Balance April 1, 2023	315.4	$ 3.2	$ 9,692.4	$ 9,741.7	$ (178.0)	(106.9)	$ (7,108.6)	$ 6.9	$ 12,157.6
Net earnings	-	-	-	209.6	-	-	-	0.2	209.8
Other comprehensive income	-	-	-	-	0.2	-	-	-	0.2
Cash dividends declared ($0.24 per share)	-	-	-	(50.1)	-	-	-	-	(50.1)
Stock compensation plans	0.3	-	58.1	1.1	-	-	0.7	-	59.9
Embody, Inc. acquisition consideration	0.1	-	15.5	-	-	-	-	-	15.5
Share repurchases	-	-	-	-	-	(0.1)	(14.3)	-	(14.3)
Balance June 30, 2023	315.8	$ 3.2	$ 9,766.0	$ 9,902.3	$ (177.8)	(107.0)	$ (7,122.2)	$ 7.1	$ 12,378.6
Balance April 1, 2022	313.4	$ 3.1	$ 9,385.7	$ 9,503.1	$ (158.9)	(103.8)	$ (6,717.5)	$ 5.9	$ 12,021.4
Net earnings	-	-	-	153.7	-	-	-	0.3	154.0
Other comprehensive loss	-	-	-	-	(33.6)	-	-	-	(33.6)
Cash dividends declared ($0.24 per share)	-	-	-	(50.3)	-	-	-	-	(50.3)
Stock compensation plans	-	-	33.1	-	-	-	-	-	33.1
Balance June 30, 2022	313.4	$ 3.1	$ 9,418.8	$ 9,606.5	$ (192.5)	(103.8)	$ (6,717.5)	$ 6.2	$ 12,124.6
Balance January 1, 2023	313.8	$ 3.1	$ 9,504.4	$ 9,559.3	$ (179.3)	(104.8)	$ (6,867.2)	$ 6.7	$ 12,027.0
Net earnings	-	-	-	442.1	-	-	-	0.5	442.6
Other comprehensive income	-	-	-	-	1.5	-	-	-	1.5
Cash dividends declared ($0.24 per share)	-	-	-	(100.5)	-	-	-	-	(100.5)
Stock compensation plans	0.8	-	113.5	1.4	-	-	1.0	-	115.9
Embody, Inc. acquisition consideration	1.2	0.1	150.4	-	-	-	-	-	150.5
Share repurchases	-	-	(2.3)	-	-	(2.2)	(256.0)	-	(258.3)
Balance June 30, 2023	315.8	$ 3.2	$ 9,766.0	$ 9,902.3	$ (177.8)	(107.0)	$ (7,122.2)	$ 7.1	12,378.6
Balance January 1, 2022	312.8	$ 3.1	$ 9,314.8	$ 10,292.2	$ (231.6)	(103.8)	$ (6,717.8)	$ 5.7	$ 12,666.4
Net earnings	-	-	-	167.9	-	-	-	0.5	168.4
Other comprehensive loss	-	-	-	-	(22.0)	-	-	-	(22.0)
Cash dividends declared ($0.24 per share)	-	-	-	(100.6)	-	-	-	-	(100.6)
Reclassifications of net investment hedges	-	-	-	-	25.9	-	-	-	25.9
Spinoff of ZimVie Inc.	-	-	-	(753.1)	35.2	-	-	-	(717.9)
Stock compensation plans	0.6	-	104.0	0.1	-	-	0.3	-	104.4
Balance June 30, 2022	313.4	$ 3.1	$ 9,418.8	$ 9,606.5	$ (192.5)	(103.8)	$ (6,717.5)	$ 6.2	$ 12,124.6

The accompanying notes are an integral part of these condensed consolidated financial statements.

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions, unaudited)

	For the Six Months Ended June 30,	
	2023	2022
Cash flows provided by (used in) operating activities from continuing operations:		
Net earnings from continuing operations	$ 442.6	$ 227.2
Adjustments to reconcile net earnings from continuing operations to cash provided by operating activities from continuing operations:		
Depreciation and amortization	469.3	466.5
Share-based compensation	58.9	50.8
Intangible asset impairment	-	3.0
(Gain) loss on investment in ZimVie Inc.	(2.5)	84.3
Changes in operating assets and liabilities, net of acquired assets and liabilities		
Income taxes	13.8	13.0
Receivables	8.0	(81.8)
Inventories	(148.0)	(26.4)
Accounts payable and accrued liabilities	(185.2)	(49.9)
Other assets and liabilities	(1.3)	(25.5)
Net cash provided by operating activities from continuing operations	655.6	661.2
Cash flows provided by (used in) investing activities from continuing operations:		
Additions to instruments	(168.3)	(120.6)
Additions to other property, plant and equipment	(144.0)	(77.3)
Net investment hedge settlements	19.0	33.9
Acquisition of intellectual property rights	(73.3)	-
Business combination investments, net of acquired cash	(32.9)	(99.8)
Other investing activities	7.0	(60.5)
Net cash used in investing activities from continuing operations	(392.5)	(324.3)
Cash flows provided by (used in) financing activities from continuing operations:		
Proceeds from revolving facility	570.0	220.0
Payments on revolving facility	(425.0)	(220.0)
Redemption of senior notes	(86.3)	(750.0)
Payment on term loan	(33.9)	-
Dividends paid to stockholders	(100.6)	(100.5)
Proceeds from employee stock compensation plans	61.1	45.0
Distribution from ZimVie Inc.	-	540.6
Business combination contingent consideration payments	(10.3)	-
Deferred business combination payments	(4.0)	-
Repurchase of common stock	(281.9)	-
Other financing activities	(5.2)	(3.5)
Net cash used in financing activities from continuing operations	(316.1)	(268.4)
Cash flows provided by (used in) discontinued operations:		
Net cash used in operating activities	-	(71.5)
Net cash used in investing activities	-	(7.2)
Net cash used in financing activities	-	(68.1)
Net cash used in discontinued operations	-	(146.8)
Effect of exchange rates on cash and cash equivalents	(2.9)	(13.8)
Decrease in cash and cash equivalents	(55.9)	(92.1)
Cash and cash equivalents, beginning of year (includes $100.4 at January 1, 2022 of discontinued operations cash)	375.7	478.5
Cash and cash equivalents, end of period	$ 319.8	$ 386.4

The accompanying notes are an integral part of these condensed consolidated financial statements.

ZIMMER BIOMET HOLDINGS, INC. AND SUBSIDIARIES
NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

The financial data presented herein is unaudited and should be read in conjunction with the consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2022.

In our opinion, the accompanying unaudited condensed consolidated financial statements include all adjustments, consisting of only normal recurring adjustments, necessary for a fair statement of the financial position, results of operations and cash flows for the interim periods presented. The December 31, 2022 condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America ("GAAP"). Results for interim periods should not be considered indicative of results for the full year.

Amounts reported in millions within this Quarterly Report on Form 10-Q are computed based on the actual amounts. As a result, the sum of the components may not equal the total amount reported in millions due to rounding. In addition, certain columns and rows within tables may not sum to the totals due to the use of rounded numbers. Percentages presented are calculated from the underlying unrounded amounts.

Risks and Uncertainties - Our results have been and may continue to be impacted by the COVID-19 global pandemic. The vast majority of our net sales are derived from products used in elective surgical procedures which may get deferred due to precautions in certain markets if there is a surge in infections. Although the effects of the COVID-19 pandemic on our operating results continue to subside, the pandemic could still have an unfavorable effect on our financial position, results of operations and cash flows in the near term.

Spinoff - On March 1, 2022, we completed the previously announced separation of our spine and dental businesses into a new public company through the distribution by Zimmer Biomet of 80.3% of the outstanding shares of common stock of ZimVie Inc. ("ZimVie") to Zimmer Biomet's stockholders. We disposed of our remaining shares of ZimVie in February 2023. The historical results of our spine and dental businesses that were contributed to ZimVie in the spinoff have been reflected as discontinued operations in our condensed consolidated financial statements through the date of the spinoff in 2022 as the spinoff represented a strategic shift in our business that had a major effect on operations and financial results. The disclosures presented in our notes to the interim condensed consolidated financial statements are presented on a continuing operations basis.

The words "we," "us," "our" and similar words, "Zimmer Biomet" and "the Company" refer to Zimmer Biomet Holdings, Inc. and its subsidiaries. "Zimmer Biomet Holdings" refers to the parent company only.

We reclassified the loss on investment in ZimVie in the prior period condensed consolidated statement of cash flows to conform to the current period presentation.

2. Discontinued Operations and Related ZimVie Matters

On March 1, 2022, we completed the previously announced separation of our spine and dental businesses through the distribution of 80.3% of the outstanding shares of common stock of ZimVie to our stockholders at the close of business on February 15, 2022 (the "Record Date"). The distribution was made in the amount of one share of ZimVie common stock for every ten shares of our common stock owned by our stockholders at the close of business on the Record Date. Fractional shares of ZimVie common stock were not issued but instead were aggregated and sold in the open market with the proceeds being distributed pro rata in lieu of such fractional shares.

In the fourth quarter of 2021, ZimVie entered into a credit agreement with a financial institution providing for revolving loans of up to $175.0 million and term loan borrowings of up to $595.0 million. On February 28, 2022, prior to separation, ZimVie borrowed the entire $595.0 million available under the term loan. Approximately $540.6 million of this amount was paid by ZimVie to Zimmer Biomet in the form of a dividend at separation which is included in our cash flows from financing activities in the condensed consolidated statements of cash flows. We used proceeds from the dividend, along with cash on hand and proceeds from a draw on our revolving credit facility, to repay our 3.150% Senior Notes due 2022 which had an outstanding principal balance of $750.0 million.

In connection with the spinoff, we entered into definitive agreements with ZimVie that, among other things, set forth the terms and conditions of the separation and distribution. These agreements include a Transition Services Agreement (the "TSA"), a Transition Manufacturing and Supply Agreement (the "TMA"), a Reverse Transition Manufacturing and Supply Agreement (the "Reverse TMA"), and various other agreements each dated as of March 1, 2022.

Pursuant to the TSA, both we and ZimVie agree to provide certain services to each other, on an interim, transitional basis from and after the separation and the distribution. The services include certain regulatory services, commercial services, operational services, tax services, clinical affairs services, information technology services, finance and accounting services and human resource and employee benefits services. The remuneration to be paid for such services is generally intended to allow the company providing the services to recover all of its costs and expenses of providing such services. The TSA will terminate on the expiration of the term of the last service provided thereunder, which will generally be no later than March 31, 2025. However, we expect most TSA services will be completed by the end of 2023.

Pursuant to the TMA and the Reverse TMA, Zimmer Biomet or ZimVie, as the case may be, will manufacture or cause to be manufactured certain products for the other party, on an interim, transitional basis. Pursuant to such agreements, Zimmer Biomet or ZimVie, as the case may be, will be required to purchase certain minimum amounts of products from the other party. Each of the TMA and the Reverse TMA has a two-year term, with a one-year extension possible upon mutual agreement of the parties.

We recognize any gains or losses from the TSA and TMA agreements in the Acquisition, integration, divestiture and related line item in our condensed consolidated statements of earnings. Amounts included in the condensed consolidated statements of earnings related to these agreements for the three and six-month periods ended June 30, 2023 and 2022 were immaterial.

We initially retained approximately 5.1 million common shares of ZimVie in connection with the spinoff, representing approximately 19.7 percent of ZimVie's outstanding common shares on the separation date. Given our inability to exert significant influence over ZimVie, we recognized this investment at fair value in prepaid expenses and other current assets on our condensed consolidated balance sheet. Changes to the fair value of the investment were recognized in non-operating other (expense) income, net, in subsequent periods. We disposed of these shares in February 2023. In the six-month period ended June 30, 2023, we recognized a gain of $2.5 million related to our investment in ZimVie. In the three and six-month periods ended June 30, 2022, we recognized losses of $33.3 million and $84.3 million, respectively, related to our investment in ZimVie.

On August 31, 2022, we borrowed an aggregate principal amount of $83.0 million under a short-term credit agreement (the "Short-Term Term Loan") with a third-party financial institution, the proceeds of which were used to repay certain of our existing indebtedness. On September 1, 2022, we entered into a forward exchange agreement and pledge agreement (collectively the "Forward Exchange Agreement") with the same financial institution to deliver to them our 5.1 million shares of ZimVie common stock in the first quarter of 2023. We pledged our 5.1 million shares of ZimVie common stock to the financial institution as collateral for our obligations under the Short-Term Term Loan and the Forward Exchange Agreement.

In February 2023, we repaid in full the Short-Term Term Loan by transferring our ZimVie common shares to the financial institution counterparty to settle the Forward Exchange Agreement and by paying $33.9 million in cash, representing an amount determined by the difference between the average daily volume-weighted average price of the ZimVie shares over the outstanding term of the Forward Exchange Agreement and the principal amount of $83.0 million. The transfer of our ZimVie common shares as part of the settlement resulted in a $49.1 million noncash financing activity for the six-month period ended June 30, 2023.

The Forward Exchange Agreement was accounted for at fair value, with changes in fair value recognized in non-operating other (expense) income, net and was included in the net gain related to our investment in ZimVie for the six month-period ended June 30, 2023, as discussed above. The most significant input into the valuation of the Forward Exchange Agreement was the market price of the ZimVie shares. The fair value of the Forward Exchange Agreement as of December 31, 2022 was $1.1 million and was included within prepaid expenses and other current assets on our condensed consolidated balance sheet.

As discussed in Note 1, Basis of Presentation, the results of our spine and dental businesses have been reflected as discontinued operations through the date of the spinoff in the prior year period. Details of loss from discontinued operations included in our condensed consolidated statements of earnings are as follows (in millions):

	Six Months Ended June 30, 2022
Net Sales	$ 147.8
Cost of products sold, excluding intangible asset amortization	53.5
Intangible asset amortization	14.0
Research and development	10.5
Selling, general and administrative	89.4
Restructuring and other cost reduction initiatives	0.4
Acquisition, integration, divestiture and related	40.9
Other expense, net	0.3
Loss from discontinued operations before income taxes	(61.2)
Benefit for income taxes from discontinued operations	(2.4)
Loss from discontinued operations, net of tax	$ (58.8)

In a pro rata spinoff of consolidated subsidiaries, the distribution of the assets and liabilities are recognized through equity instead of net earnings. Accordingly, we recognized the distribution of net assets to ZimVie in retained earnings. Additionally, the dividend we received from ZimVie at the separation was also recognized in retained earnings.

3. Significant Accounting Policies

Use of Estimates - The accompanying unaudited condensed consolidated financial statements are prepared in conformity with GAAP, which requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We have made our best estimates, as appropriate under GAAP, in the recognition of our assets and liabilities. Actual results could differ materially from these estimates.

Accounting Pronouncements Not Yet Adopted - There are no recently issued accounting pronouncements that we have not yet adopted that are expected to have a material effect on our financial position, results of operations or cash flows.

4. Revenue

Net sales by geography are as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
United States	$ 1,068.9	$ 1,017.6	$ 2,129.2	$ 1,958.8
International	800.7	764.2	1,571.4	1,486.2
Total	$ 1,869.6	$ 1,781.8	$ 3,700.6	$ 3,445.0

Net sales by product category are as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Knees	$ 771.4	$ 704.9	$ 1,533.9	$ 1,367.7
Hips	504.3	487.2	997.1	938.2
S.E.T.	442.7	446.4	876.1	863.2
Other	151.2	143.3	293.5	275.9
Total	$ 1,869.6	$ 1,781.8	$ 3,700.6	$ 3,445.0

S.E.T. includes sales from our Sports Medicine, Extremities, Trauma, Craniomaxillofacial and Thoracic ("CMFT") product categories. Other includes sales from our Technology, Surgical and Bone Cement product categories.

This net sales presentation differs from our reportable operating segments, which are based upon our senior management organizational structure and how we allocate resources toward achieving operating profit goals. Each of our reportable operating

segments sells all the product categories noted above. Accordingly, the only difference from the presentation above and our reportable operating segments are the geographic groupings.

5. Restructuring

In December 2021, our management approved a global restructuring program (the "2021 Restructuring Plan") intended to further reduce costs and to reorganize our global operations in preparation for the spinoff of ZimVie. The 2021 Restructuring Plan is expected to result in total pre-tax restructuring charges of approximately $185 million. The pre-tax restructuring charges consist of employee termination benefits; contract terminations for sales agents; and other charges, such as consulting fees and project management expenses. The following table summarizes the liabilities recognized related to the 2021 Restructuring Plan (in millions):

	Employee Termination Benefits	Contract Terminations	Other	Total
Expenses incurred in the three months ended June 30, 2023	$ 1.5	$ 1.9	$ 2.6	$ 6.0
Balance, December 31, 2022	$ 10.5	$ 25.0	$ 3.1	$ 38.6
Expenses incurred in the six months ended June 30, 2023	3.9	16.2	4.1	24.2
Cash payments	(6.6)	(17.7)	(3.1)	(27.4)
Foreign currency exchange rate changes	0.2	0.6	-	0.8
Balance, June 30, 2023	$ 8.0	$ 24.1	$ 4.1	$ 36.2
Expense incurred since the start of the 2021 Restructuring Plan	$ 57.0	$ 68.0	$ 31.0	$ 156.0
Expense estimated to be recognized for the 2021 Restructuring Plan	$ 70.0	$ 80.0	$ 35.0	$ 185.0

In December 2019, our Board of Directors approved, and we initiated, a global restructuring program (the "2019 Restructuring Plan") with an objective of reducing structural costs to allow us to further invest in higher priority growth opportunities. The 2019 Restructuring Plan is expected to result in total pre-tax restructuring charges of approximately $350 million. The pre-tax restructuring charges consist of employee termination benefits; contract terminations for facilities and sales agents; and other charges, such as consulting fees, project management expenses and relocation costs, including costs to close a manufacturing facility. The following table summarizes the liabilities recognized related to the 2019 Restructuring Plan (in millions):

	Employee Termination Benefits	Contract Terminations	Other	Total
Expenses incurred in the three months ended June 30, 2023	$ (1.1)	$ -	$ 9.4	$ 8.3
Balance, December 31, 2022	$ 28.9	$ 9.0	$ 6.4	$ 44.3
Expenses incurred in the six months ended June 30, 2023	(1.1)	-	15.5	14.4
Cash payments	(2.5)	(1.9)	(17.4)	(21.8)
Foreign currency exchange rate changes	0.9	-	0.1	1.0
Balance, June 30, 2023	$ 26.2	$ 7.1	$ 4.6	$ 37.9
Expense incurred since the start of the 2019 Restructuring Plan	$ 107.2	$ 35.0	$ 150.1	$ 292.3
Expense estimated to be recognized for the 2019 Restructuring Plan	$ 135.0	$ 35.0	$ 180.0	$ 350.0

We do not include restructuring charges in the operating profit of our reportable segments.

In our condensed consolidated statement of earnings, we report restructuring charges in our "Restructuring and other cost reduction initiatives" financial statement line item. We report the expenses for other cost reduction and optimization initiatives with restructuring expenses because these activities also have the goal of reducing costs across the organization. However, since the cost reduction initiative expenses are not considered restructuring, they have been excluded from the amounts presented in this note.

6. Inventories

	June 30, 2023	December 31, 2022
	(in millions)	
Finished goods	$ 1,727.2	$ 1,655.0
Work in progress	256.3	230.9
Raw materials	292.3	261.3
Inventories	$ 2,275.8	$ 2,147.2

7. Property, Plant and Equipment

	June 30, 2023	December 31, 2022
	(in millions)	
Land	$ 17.6	$ 19.2
Buildings and equipment	2,151.2	2,093.4
Capitalized software costs	541.9	518.2
Instruments	3,808.0	3,683.5
Construction in progress	198.6	144.1
	6,717.3	6,458.4
Accumulated depreciation	(4,742.3)	(4,585.9)
Property, plant and equipment, net	$ 1,975.0	$ 1,872.5

We had $15.7 million and $17.0 million of property, plant and equipment included in accounts payable as of June 30, 2023 and December 31, 2022, respectively.

8. Acquisitions

On February 14, 2023, we completed the acquisition of all the outstanding shares of Embody, Inc. ("Embody"), a medical device company focused on soft tissue healing, that expands our portfolio for the sports medicine market. Initial consideration consisted of the issuance of 1.1 million shares of our common stock valued at $135.0 million and $19.5 million of cash for a total value of $154.5 million. The fair value of our common stock was determined to be $127.34 per share, which represented the average of our high and low stock prices on the acquisition date. To minimize dilution from issuing shares for the Embody acquisition, we repurchased 1.9 million shares of our common stock in the three-month period ended March 31, 2023. The Embody acquisition includes additional consideration of up to $120.0 million in fair value of our common shares and cash, subject to achieving a future regulatory milestone after closing and commercial milestones based on sales growth over a three-year period. We assigned a fair value of $94.0 million for this contingent consideration as of the acquisition date. The estimated fair value of the contingent consideration liability was calculated based on the probability of achieving the specified regulatory milestone and by simulating numerous potential outcomes for the commercial milestones and discounting to present value the estimated payments.

On April 28, 2023, we completed the acquisition of all the outstanding shares of a privately held orthopedics medical device company that expands our portfolio in the orthopedics market ("April acquisition"). The initial consideration consisted of $15.0 million of cash and includes consideration of up to $8.0 million in cash, subject to achieving future regulatory milestones.

These acquisitions are collectively referred to in this report as the "2023 acquisitions". Refer to Note 11 for information regarding the issuance of common stock and cash payments related to the contingent consideration liabilities that have occurred subsequent to the acquisition dates.

The goodwill related to the 2023 acquisitions represents the excess of the consideration transferred over the fair value of the net assets acquired. The goodwill related to the 2023 acquisitions is generated from the operational synergies and cross-selling opportunities we expect to achieve from the technologies acquired. The goodwill related to the 2023 acquisitions is not expected to be deductible for tax purposes. The goodwill related to the Embody acquisition is included in the Americas operating segment and the Americas Orthopedics reporting unit. The goodwill related to the April acquisition is included in the Asia Pacific operating segment and reporting unit. The goodwill related to the 2023 acquisitions was the only significant activity related to our consolidated goodwill

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NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Emmaus Medical, Inc.

Physical Address: 21250 Hawthorne Blvd., Suite 800

City: Torrance State: CA Zip: 90503

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 310-214-0065 Website: _____

Name of Designated Representative (DR): Charles W Stark

Licensing Company Email: cfine@emmausmedical.com DR Email: _____

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Emmaus Life Sciences, Inc.

Corporation/Organization Name: Emmaus Medical, Inc.

Mailing Address: 21250 Hawthorne Blvd., Suite 800

City: Torrance State: CA Zip: 90503

Telephone: 310-214-0065 Email: wlee@emmausmedical.com

Contact Person Name: Willis Lee

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Not Traded	Partnership	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Emmaus Medical, Inc.

Facility Name

Willis Lee

Print Name of Authorized Person Submitting Application

Willi C L

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

10/26/2023

Date

Board Use Only	Date Received: _____	Amount: _____

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through November 09, 2023

You have searched Finished drug products

Search Results: *'Endari'*

Back to Search Page () | **Search Again ()**

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
– Endari	42457-420-60	5 g/1	POWDER, FOR SOLUTION	ORAL	NDA208587	Emmaus Medical, Inc.	42457-420	Glutamine	GLUTAMINE	HUMAN PRESCRIPTION DRUG	07/07/2017	N/A

Sample Package No

Listing Record Certified Through: 12/31/2023

Showing 1 to 1 of 1 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Verified
M.H 12/7/23

Emmaus Medical, Inc.
21250 Hawthorne Blvd., Suite 800
Torrance, CA 90503

List of all Officers and Directors:

Willis Lee – co-President, COO, Director

George Sekulich – co-President, Chief Commercial Officer

Yasushi Nagasaki – CFO

Charles Stark – SVP of Medical Affairs, Research and Regulatory

Wei Peu Zen – Director

Ian Zwicker – Director

Yutaka Niihara – Director

Emmaus Medical, Inc.
21250 Hawthorne Blvd., Suite 800
Torrance, CA 90503

List of all partners and their percent of ownership:

Emmaus Life Sciences, Inc. – 100% Ownership

Secretary of State
Certificate of Status

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

Entity Name:	EMMAUS MEDICAL, INC.
Entity No.:	2565518
Registration Date:	11/19/2003
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

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

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 29, 2023.

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

Certificate No.: 148912435

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

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

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

October 16, 2023

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: EMMAUS MEDICAL INC

License Type: WHOLESALER

License Number: WLS 6735

Status: ACTIVE

Issue Date: 02/03/2016

Expiration Date: 02/01/2024

Address of Record: 21250 HAWTHORNE BLVD., STE 800 TORRANCE, CA 90503

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

LICENSE NO. WLS 6735
RECEIPT NO. 30280327

VALID UNTIL FEBRUARY 01, 2024

EMMAUS MEDICAL INC
21250 HAWTHORNE BLVD., STE 800
TORRANCE CA 90503-5513

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

02/06/23
02/06/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) WLS

NEVADA STATE BOARD OF PHARMACY

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

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJC5464

Application/License No. _____

Emmaus Medical, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 21250 Hawthorne Blvd., Suite 800, Torrance, CA 90503 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza, Hartford, Connecticut. 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 3, 2023 (Effective Date).

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

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 4th day of October, 2023.

APPLICANT/PRINCIPAL

Emmaus Medical Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Bonnie Rice, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Cindy E. Johnson

Witness Andrea Allman

Countersigned by:

N.A.
Nevada Resident Agent

POWER OF ATTORNEY

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

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

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

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

Bonnie Rice

of

Knoxville, TN

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

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

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

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

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

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of October 4, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Emmaus Medical, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 21250 Hawthorne Blvd. Ste 800

City: Torrance State: CA Zip: 90503

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 310-214-0065 Website:

Licensing Company Email: Wlee@emmauslifesciences.com

Section 2: Personal Information

First: Charles Middle: William Last: Stark

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

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

Mailing Address: 21250 Hawthorne Blvd. Ste 800

City: Torrance State: CA Zip: 90503

Telephone: 310-310-4060 Email: cstark@emmauslifesciences.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Roosevelt High School		09/70 - 06/73	
Address	**City**	**State**	**Zip**
456 S. Mathews Street	Los Angeles	CA	90033
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/73 - 06/78	
Address	**City**	**State**	**Zip**
3400 South Figueroa Street	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
Bachelors in Arts			

School Name		From - To (MM/YY – MM/YY)	
University of Southern California		09/78 - 06/82	
Address	**City**	**State**	**Zip**
1985 Zonal Avenue	Los Angeles	CA	90033
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/89 - Current	[redacted]	San Pedro	CA	90731
From - To (MM/YY – MM/YY)	Address	City	State	Zip
	N/A			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Emmaus Medical, Inc.			11/13 - Present	
Business Address		**City**	**State**	**Zip**
21250 Hawthorne Blvd. Ste. 800		Torrance	CA	90503
Phone	**Title**		**Number of Employed Hours**	
310-214-0065	Sr VP Clinical Development and Medical Affairs		20400	
Description of Duties				
Oversight of drug distribution, handling, and storage.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

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

I, Charles Stark, **certify that as the designated representative for**

Emmaus Medical, Inc.,

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

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

Charles Stark

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/26/2023

Date

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

Charles Stark

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/26/2023

Date

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

State of CALIFORNIA, ss. County of LOS ANGELES

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

Original Signature

9/26/2023

Date

Subscribed and Sworn to before me this 26 day of September, 2023.

Notary Public Signature

MARIA ALEJANDRA KAISER NOTARY PUBLIC - CALIFORNIA Los Angeles County Comm. #2449501 My Comm. Expires June 6, 2027

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

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

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 26 (Date) day of September (Month), 2023 (Year), by

(1) Charles Stark

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

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

MARIA ALEJANDRA KAISER NOTARY PUBLIC - CALIFORNIA Los Angeles County Comm. #2449501 My Comm. Expires June 6, 2027

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

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Emmaus Medical, Inc.
21250 Hawthorne Blvd., Suite 800
Torrance, CA 90503

List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Employee – see attached list

Agent – Corporation Service Company

Independent Contractor – N/A

Consultant – Brian Berman and Nirmish Shah

Guardian – N/A

Personal Representative – N/A

Lender or holder of indebtedness of the applicant – see attached list

	First Name	Last Name
1	Albert	Niihara
2	Andrew	Clemons
3	Bernard	Eyssalenne
4	Brandon	Thomas
5	Brian	Aquino
6	Chanci	Fine
7	Charlie	Stark
8	Evan	Garner
9	George	Sekulich
10	Hiroko	Huynh
11	Jason	Deshefy
12	Jason	Goodrow
13	Joan	Oliva
14	Joseph	Becerra
15	Jun	Haneda
16	Karen	Gant
17	Kazon	Neely
18	Kazue	Sashida
19	Latoya	Robinson
20	Mack	Wilson
21	Patrick	Price
22	Paul	Shitabata
23	Quinton	Nealy
24	Rafael	Razon
25	Rajani	Singh
26	Richard	O'Neal
27	Robert (Bob)	Lavelle
28	Timothy	Ayers
29	Sam	Kwak
30	Sara	Springer
31	Sonoma	Saito
32	Sophia	Lin
33	Steven	Frankowitz
34	Veronica	Boone
35	William	Weaver
36	Willis	Lee
37	Yasushi	Nagasaki
38	Yusra	Abidi
39	Yuri	Yamagata

	Loan Details [redacted]
Convertible Notes	
PP 2021	Briana Lee
PP 2021	Mee Sook Lee
PP 2021	Susie Lee
PP 2021	Brian Oum
PP 2021	Yun Mi Lee
PP 2021	Yoon Taik Kwon
PP 2021	Mijin Lee
PP 2021	Sung Jun Oum
PP 2021	Miriam Lee
PP 2021	Kevin Hsu
PP 2021	Dong Kwan Kim
PP 2021	Dong Seon Kim
PP 2021	Dong Won Kim
PP 2021	Sung Hyuk Lee
PP 2021	Yoon Min Park
PP 2021	Grace Hyosik Chang
PP 2021	Namsik Oh
PP 2021	Sam Jong Kim
PP 2021	Jin Sok Byun
PP 2021	Ming Wen Cao
	Wei Peu Zen
Amend 4	Wealth Threshold Limited
	Smart Start Investments Limited
	Subtotal
Promissory Notes	
	EMJ (Shigeru Matsuda)
	Willis Lee
	Soomi Niihara
	Hope International Hospice, Inc.
	Hope International Hospice, Inc.
	Soomi Niihara
	Osato Medical Clinic
	Hope International Hospice, Inc.
	Hope International Hospice, Inc.
	Wei Pei Zen
	Albert Niihara
	Willis Lee
	Eastwind, Ltd.
	Albert Niihara
	Hope International Hospice, Inc.
	Dr. Yutaka and Soomi Niihara
	Dr. Yutaka and Soomi Niihara
	Dr. Yutaka and Soomi Niihara
	Hope International Hospice, Inc.

	Seah Lim
	Hope International Hospice, Inc.
	The Shitabata Family Trust
	EMJ (Shigeru Matsuda)
	Hope International Hospice, Inc.
	Dr. Yutaka and Soomi Niihara
	Eastwind, Ltd.
	EMJ (Shigeru Matsuda)
Merchant Cash Advance (MCA) Loans	
	Maximcash Management Group LLC
	APEX Funding
	Slate
	FundKite 2
	CouldFund 2

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

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

Section 1: General Information

Facility Name: Impladent Ltd

Physical Address: 86-90 188th St.

City: Jamaica State: NY Zip: 11423

Mailing Address (if different from physical address): 86-90 188th Street

City: Queens State: NY Zip: 11423

Telephone: 718-465-1810 Website: https://www.impladentltd.com/

Name of Designated Representative (DR): Andrew Valen

Licensing Company Email: andrew@impladentltd.com DR Email: andrew@impladentltd.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Dentists		☒ Others: Self-Distributor

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

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

Name: No suppliers sold, dispensed or distributed within the past year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NY

Parent Company (if any): Solmetex LLC

Corporation/Organization Name: Impladent, Ltd

Mailing Address: 86-90 188th Street

City: Queens State: NY Zip: 11423

Telephone: 617-417-1993 Email: lnagel@solmetex.com

Contact Person Name: Lauren Nagel

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Impladent Ltd
Facility Name

Andrew Valen
Print Name of Authorized Person Submitting Application

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

11/29/23
Date

Board Use Only	Date Received: 11/9/24	Amount: $1000 - check 649

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
IMPLADENT, LTD.
86-90 188 STREET
HOLLIS, NY 11423
Registration Number: 2431866
FEI Number*: 2431866
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
IMPLADENT, LTD.[6]
86-90 188 STREET
Jamaica, NY US 11423
Owner/Operator Number: 2431866[7]

Official Correspondent:
Maurice Valen
86-90 188 STREET
Jamaica, NY 11423
Phone: 718-4651810

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 12/11/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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start_search=1&establishmentName=@Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2431866&OwnerOperator

IMPLADENT LTD.

Company Information

Company Name:	Impladent Ltd.
Licensing Email:	andrew@impladentltd.com
Address:	86-90 188th St.
City, State, Zip:	Jamaica, NY 11423
Phone:	718-465-1810
Tax ID:	11-2929171
State of Formation:	New York
Date Incorporated:	September 15, 1988

Ownership Information

Impladent Ltd. Is a privately held corporation 100% owned by Solmetex LLC (EIN No. 37-1738231), which is a Limited Liability Company located at 4 Mt Royal Ave. in Marlborough, MA 01752.

Officers

Andrew Valen, General Manager
Business Address:
86-90 188th St.
Jamaica, NY 11423
Business Phone:
718-465-1810

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

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

Entity Name:	IMPLADENT, LTD.
DOS ID Number:	1291882
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	09/15/1988
Statement Status:	CURRENT
Statement Due Date:	09/30/2024

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

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 26, 2023 at 09:48 A.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100004372404 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

From: andrew@impladentltd.com
To: Couch, Daniel
Subject: FW: Medical Devices
Date: Friday, July 14, 2023 2:16:18 PM
Attachments: image001.jpg

[External]

Andrew Valen, MS, MHA | President | Impladent Ltd | andrew@impladentltd.com | Office: (718) 465-1810 | fax (929) 356-9990 | 86-90 188th st, Jamaica, NY, 11423 | www.impladentltd.com

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From: PHARMBD <PHARMBD@nysed.gov>
Sent: Thursday, April 6, 2023 4:57 PM
To: andrew@impladentltd.com
Subject: RE: Medical Devices

Dear Andrew,

This Office goes by what the FDA classifies your devices as in terms of whether or not a NYS registration is required for you to do business.

A nonresident establishment must be registered with the NYS Board of Pharmacy if it ships, mails, delivers, invoices or provides samples of prescription drugs into NYS.

The NYS Board of Pharmacy reviews applications on a *"case by case basis"* for medical device distributors that ships, mails, delivers, invoices or provides samples of prescription devices that contain the Federal Law caution: '*Federal law prohibits dispensing without a prescription*' .

If an establishment is wholesaling durable medical equipment (DME) or devices which do not require a prescription but instead contain a caution '*Federal law restricts this device to sale by or on the order of a physician*', there is no registration requirement with the state of New York.

What does the product label say on these devices you wish to sell? That would be a good indicator as to whether or not a registration is required.

Sincerely,
Jeffrey Fisher
Administrative Assistant Trainee 1

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

From: andrew@impladentltd.com <andrew@impladentltd.com>
Sent: Tuesday, March 28, 2023 12:53 PM
To: PHARMBD <PHARMBD@nysed.gov>
Subject: Medical Devices

Good Afternoon,

I am reaching out for clarity on the registration requirements for medical device companies. We manufacture and sell dental bone grafts which are Class II FDA cleared devices under 510(k) of the Federal Food, Drug, and Cosmetic Act. Other states specifically carve these federally cleared devices out of their Pharmacy regulations, but I wanted to check re: NY.

In the definition section 6800 and 6801 it says "This article applies to the profession of pharmacy" and says "Definition of practice of pharmacy. 1. The practice of the profession of pharmacy is defined as the administering, preparing, compounding, preserving, or the dispensing of drugs, medicines and **therapeutic devices** on the basis of prescriptions or other legal authority, and collaborative drug therapy management in accordance with the provisions of section sixty-eight hundred one-a of this article."

The Merck Manual defines therapeutic devices as orthoses, wheelchairs, walking aids, scooters and other items typically sold in a pharmacy. We are not a pharmacy, do not do business with any pharmacies and do not sell therapeutic devices, instead we sell bone grafts regulated by the FDA directly to dentists. We do not think that these regulations apply to us. Can someone there please confirm that we are not subject to these regulations. In searching for other business entities

registered as Pharmacies, I cannot find similar medical device companies – but out of an abundance of caution, I wanted to ask. More broadly, are there other purely medical device companies that register under these regulations?

Thanks,

Andrew

Andrew Valen, MS, MHA | President | Impladent Ltd | andrew@impladentltd.com | Office: (718) 465-1810 | fax (929) 356-9990 | 86-90 188th st, Jamaica, NY, 11423 | www.impladentltd.com

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GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	810016082
For	NV Pharmaceutical Wholesaler Surety Bond
Dated effective	10/12/2023 (MONTH, DAY, YEAR)
Executed by	Solmetex, as Principal, (PRINCIPAL)
And by	Atlantic Specialty Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

Adding Facility per Schedule A

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **10/12/2023**

(MONTH, DAY, YEAR)

Signed and Sealed **10/24/2023**

(MONTH, DAY, YEAR)

Solmetex
PRINCIPAL

BY _____

TITLE

Atlantic Specialty Insurance Company
SURETY

BY _____

Sarah Murtha, ATTORNEY-IN-FACT

Schedule A

ADDENDUM TO BOND NO. 810016082

(Locations updated: 10/24/2023)

ADDRESS OF OFFICE(S) LICENSED / TO BE LICENSED:

Principal:
Solmetex
4 Mount Royal Avenue, Marlborough, MA 01752-1961

Additional Facility:
Impladent
86-90 188th St
Queens, NY 11423

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Connor Wolpert, Doritza Mojica, Gentry Stewart, Jennifer Godere, Jonathan Gleason, Joshua Sanford, Kathryn Pryor, Michelle Anne McMahon, Nicholas Miller, Richard Hackner, Robyn Salley, Sarah Murtha**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON DWAN NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2025

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 24th day of October, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2025

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@intactinsurance.com

Telephone: +1 860-329-1458
Website: wtwco.com
E-mail: kristopher.pisano@wtwco.com

October 24, 2023

Solmetex
4 Mt Royal Ave
Marlborough, MA 01752

RE: **Bond Number: 810016082**
Obligee: Nevada State Board of Pharmacy
Description: NV Pharmaceutical Wholesaler Surety Bond
Commission: 30%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice for this bond is enclosed or will be sent to you under separate cover. Please note the premium payment for this bond is due upon receipt.

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson can collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: http://www.willis.com/About_Willis/The_Willis_Way/Commission_Rates/.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Kristopher Pisano

ACORD

IMPLA-1

0454 OP ID: EC

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 06/27/2023

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

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

PRODUCER Nielson & Associates, LTD 19 Park Ave Manhasset, NY 11030 Kevin M. Kelly 516-627-0822	CONTACT NAME: Kevin M. Kelly PHONE (A/C, No, Ext): 516-627-0822 FAX (A/C, No): 516-627-5247 E-MAIL ADDRESS:
INSURED Impladent Ltd Attn: Andrew Valen 86-90 188th Street Jamaica, NY 11423	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Continental Casualty Company INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY							
	CLAIMS-MADE X OCCUR			6021166488	07/26/2023	07/26/2024	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ Excluded
	OTHER:							$
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	ANY AUTO			6021166488	07/26/2023	07/26/2024	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

Proof Insurance

CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

James A. Shirley

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Impladent Ltd MDEG License # (if applicable) _____

Physical Address 86-90 188th St.

City Jamaica State NY Zip 11423

Mailing Address (if different from physical address) 86-90 188th Street

City Queens State NY Zip 11423

Telephone 718-465-1810 Website https://www.impladentltd.com/

Licensing Company Email andrew@impladentltd.com

Section 2: Personal Information

First Andrew Middle William Last Valen

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

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

Mailing Address 86-90 188th Street

City Queens State NY Zip 11423

Telephone 718-465-1810 Email andrew@impladentltd.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
New York University		8/13 to 5/16	
Address	**City**	**State**	**Zip**
345 E 24th St.	New York	NY	10010
Diploma/Degree obtained, if any			
Master of Healthcare Administration (MHA), Business Administration &			

School Name		From - To (MM/YY – MM/YY)	
Cornell University		08/04 - 05/06	
Address	**City**	**State**	**Zip**
616 Thurston Ave.	Ithaca	NY	14850
Diploma/Degree obtained, if any			
Master of healthcare Administration (MHA), Business			

School Name		From - To (MM/YY – MM/YY)	
Tufts University		00 - 04	
Address	**City**	**State**	**Zip**
419 Boston Ave.	Boston	MA	02155
Diploma/Degree obtained, if any			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21/2013 Current	[redacted]	Hollis Hills	NY	11364
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Impladent, LTD			2013 - Present	
Business Address		**City**	**State**	**Zip**
86-90 188th St.		Jamaica	NY	11423
Phone	**Title**		**Number of Employed Hours**	
718-465-1810	President		6000+	
Description of Duties				
See attached resume				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/29/23
Date

I, Andrew Valen, **certify that as the MDEG Administrator for**

Impladent Ltd,

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

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

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

Andrew Valen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/7/23
Date

Board Use Only	Date Received: 12/11/23

Contact
andrew@impladentltd.com

Andrew Valen

President at Impladent Ltd.
New York, New York, United States

Experience

Impladent Ltd.

President
2013 - Present

-Responsible for business expansion initiatives as well as the development and implementation of Impladent Ltd's strategic direction.

-Develop and manage all steps of the biomaterial product cycle including conception, research and development, testing, regulatory approval, product launch and ongoing sales/marketing activities.

-Manage multiple business initiatives including identifying market opportunities, developing strategic partnerships, international business growth, marketing/ sales, production and regulatory affairs.

-Direct and oversee business operations to meet financial and strategic goals.

J.P. Morgan
Vice President - Healthcare Equities Research

2012 - 2013

-Healthcare Equities Analyst at JP Morgan Investment Bank covering both the Managed Care and Hospitals sectors.

-Member of the Institutional Investor #1 ranked Equity Research team for two separate business sectors.

-Provided coverage of eighteen healthcare services companies and conducted primary research at both the company and industry levels.

-Conveyed proprietary conclusions and investment recommendations to clients in person and through written reports.

-Created and maintained detailed industry level and company specific financial models forecasting sector trends and quarterly earnings.

UBS Investment Bank
Associate Director - Healthcare Equities Research

2010 - 2012

-Healthcare Equities Analyst covering both the Managed Care and Hospitals sectors.

-Provided coverage of nineteen healthcare services companies and conducted primary research at both the company and industry levels.

-Conveyed proprietary conclusions and investment recommendations to clients in person and through written reports.

-Created and maintained detailed company specific financial models forecasting sector trends and quarterly earnings.

-Member of research team that was ii ranked in two categories: Managed Care and Health Care Facilities.

PricewaterhouseCoopers

Senior Associate Consultant, Healthcare Practice

2006 - 2010

-Provided business advisory services specializing in Academic Medical Centers, Outpatient and physician group practices, financial turnarounds and strategic/operational planning.

-Experienced in interim management of clinic operations, process improvement, compensation planning/design and financial reporting.

-Assisted clients with the development of detailed long term strategic and business planning efforts.

Education

New York University - College of Dentistry

Master of Science (MS), Biomaterials and Biomimetics · (2016)

Cornell University

Master of Healthcare Administration (MHA), Business Administration & Policy · (2004 - 2006)

Tufts University

Bachelor of Arts (BA), Pre-Medicine/Pre-Medical Studies, Child Development · (2000 - 2004)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Impladent Ltd

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 86-90 188th St.

City Jamaica State NY Zip 11423

Mailing Address (if different from physical address) 86-90 188th Street

City Queens State NY Zip 11423

Telephone 718-465-1810 Website https://www.impladentltd.com/

Licensing Company Email andrew@impladentltd.com

Section 2: Personal Information

First Andrew Middle William Last Valen

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

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

Mailing Address 86-90 188th St.

City Jamaica State NY Zip 11423

Telephone 718-465-1810 Email andrew@impladentltd.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)	
New York University			08/13 to 05/16	
Address		City	State	Zip
345 E 24th St		New York	NY	10010
Diploma/Degree obtained, if any				
Master of Science (MS), Biomaterials and Biomimetics				
School Name			From - To (MM/YY – MM/YY)	
Cornell University			08/04 - 05/06	
Address		City	State	Zip
616 Thurston Ave.		Ithaca	NY	14850
Diploma/Degree obtained, if any				
Master of Healthcare Administration (MHA), Business Administration & Policy				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13 to Present	[redacted]	Hollis Hills	NY	11364
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Impladent, LTD			2013 - Present	
Business Address		**City**	**State**	**Zip**
86-90 188th St.		Jamaica	NY	11423
Phone	**Title**		**Number of Employed Hours**	
718-465-1810	President		6000+	
Description of Duties				
See attached Resume				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

N/A

Provide explanation below:

_____ _____

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

I, Andrew Valen, **certify that as the designated representative for**

Impladent Ltd,

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

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

Andrew Valen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/23

Date

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

Andrew Valen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/23

Date

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

State of NEW YORK, ss. County of QUEENS

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

Original Signature

11/29/23

Date

Subscribed and Sworn to before me this 29th day of NOVEMBER, 2023

AYANNA HENRY

Notary Public Signature

11.29.23 **Ayanna Henry**
Notary Public, State of New York
01HE0015061
Qualified in Queens County
Commission Expires October 27, 2027 **(Seal)**

IMPLADENT LTD
REGENERATIVE SOLUTIONS

Employee List

Andrew Valen

Lyman Tsang

Zachary Adler

Johnny Yuen

Lia Atkinson

Sean Jackson

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REGENERATIVE SOLUTIONS

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Medical Device Regulatory Audit Report

Impladent, Ltd. 0473
2022-10-11-AUR-SGSU-F004853 / 615981
From 2022-10-11 To 2022-10-14

Section 1. Audit Information

Auditing Organization **SGS United Kingdom Ltd.**

Audit Starting Date 2022-10-11 **Audit Ending Date** 2022-10-14 **Duration of Audit** (in auditor-days) 3.5

AO Audit Report Ref 615981 **Languages used during the audit** English

Audit Team

Team Member Victor M. Hernandez

Role ☒ Lead Auditor ☐ Auditor ☐ Technical Expert ☐ Auditor in training ☐ Observer ☐ Interpreter

Affiliation ○ AO Employee ◉ External Resource: Organization self employed

Section 2. Audited Facility

Name of the Audited Facility
Impladent, Ltd.

MDSAP Facility Identifier
F004853

Street Address
86-90 188 St.

Address Details (Building, Appartment, Suite #,...), as applicable

City	Country	State/Province	Zip Code
Jamaica	United States of America	New York	11423

Contact Person Name	Title	Email	Telephone
Andrew Valen	President	andrew@impladentltd.com	718.465.1810

Senior Management at the Audited Facility (Name and Title)
Maurice Valen, CEO

Facility Identification Number(s) - if no number or field is not applicable, indicate NA. Link to RA databases -> Australia | Brazil | Canada | Japan | USA

Australia - TGA	Brazil - ANVISA	Canada - Health Canada	Japan - MHLW/PMDA	USA - FDA
NA	N/A	TBD	N/A	2431866

Other Jurisdictions N/A

Section 3. Certification Schemes, Scopes & Criteria, Audit Types

MDSAP Certification Scheme ☐ Not Applicable

Audit type

○ Initial ○ Surveillance #1 ◉ Surveillance #2 ○ Recertification ○ Special ○ Unannounced ○ Mock

Specify: This audit was completed onsite

Scope of certification

Design and manufacture of Sterile bone grafts and kits for the area of bone restoration and regeneration.

Is any device-drug or device-biologic combination included in the scope of certification? ◉ Yes ○ No

☐ Is the scope of of certification revised compared to the currently valid certification (if applicable)

☒	**ISO 13485**	○ 2003 ◉ 2016
☒	**Australia**	Therapeutic Goods (Medical Devices) Regulations 2002 ☒ Schedule 3, Part 1 - Full Quality Assurance System ☐ Schedule 3, Part 4 - Production Quality Assurance Procedures
☐	**Brazil**	
☒	**Canada**	Medical Device Regulations SOR/98-282, Part 1
☐	**Japan**	
☒	**United States**	21 CFR Part 803 - Medical Device Reporting 21 CFR Part 806 - Reports of Corrections and Removals 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing ☒ 21 CFR Part 820 - Quality System Regulation ☐ 21 CFR Part 821 - Device Tracking
	Other reference doc.	N/A

CE Marking Certification Scheme ☒ Not Applicable

Other Certification Schemes ☒ Not Applicable

Section 4. Certification Holder and Multi-site Organization

Certification Holder

Is the Audited Facility the certification holder, as identified on the certification documents? (•) Yes ( ) No

Campus

Is the Audited Facility part of a campus including buildings at different addresses that were also visited during this audit? ( ) Yes (•) No

Related sites audited as part of the scope of certification (audit outcomes must be documented in separate reports)

Does the scope of certification cover sites other than the Audited Facility? ( ) Yes (•) No

Corporate Information ☐ See details in Attachment

Impladent, Ltd. is located at 86-90 188th Street Jamaica, NY 11423, US. Impladent, Ltd. is a stand alone company.

Section 5. Audit Objectives

Audit objectives shall include as applicable:

Surveillance audit: evaluation of:
- the effectiveness of the manufacturer's QMS incorporating the applicable regulatory requirements;
- the manufacturer's ability to comply with these requirements;
- new or changed product/process related technologies; and,
- new or amended product technical documentation in relation to relevant regulatory requirements.

Section 6. Audited Facility Description

Regulatory Roles played by the Audited Facility, considered in the scope of the audit

Australia	☒ Manufacturer	☐ Supplier	☐ Sponsor		
Canada	☒ Manufacturer	☐ Importer	☐ Distributor	☐ Private Label Manufacturer	☐ Regulatory Correspondent
United States	☒ Manufacturer	☐ Initial Importer	☐ Remanufacturer	☐ Manufacturer of Custom Devices	
	☐ Contract Manufacturer	☒ Repackager / Relabeler	☐ Foreign Exporter	☐ Reprocessor of Single Use Devices	
	☐ Contract Sterilizer	☐ Specification Developer	☐ US Agent	☐ US Manufacturer of Export Only Devices	
				☒ Complaint File Establishment	
Other	None				

Activities at the Audited Facility

Audited Facility Address

Impladent, Ltd. - 86-90 188 St.
, Jamaica, New York, US

☒ Design and Development	☒ Purchasing	☒ Management (regulatory affairs)
☒ Production (finished device)	☒ Production (sterilization)	☐ Servicing
☐ Production (component/sub-assembly)	☐ Production (in-process, other than sterilization)	☐ Installation
☐ Production (device-drug combination)	☐ Production (packaging / labeling)	☒ Monitoring and Measurement (verification of purchased product / processes, product)
☒ Production (device-biologic combination)	☒ Preservation (storage / delivery)	☒ Monitoring and Measurement (Final product release)
	☐ Production (refurbishment)	

Other, specify: None

Activities taking place at that address that are not included in the Scope of Certification (NA if none)

N/A

Number of staff 9 Number of shifts 1 Number of staff working in shifts 9

☒ Attach the list of medical devices relevant to each address, including for each jurisdiction the class and the marketing authorization number

Section 7. Critical Suppliers (to include outsourced processes)

☐ Not Applicable

☒ Check if Critical Supplier List is attached
Note: Suppliers that have been visited in connection with the audit of this facility must be listed below.

Organization

Address | City | State/Province | Zip Code | Country

Products or services used in audited processes

Was the supplier visited jointly with the Audited Facility? ○ Yes ◉ No

Section 8. Audit History (All Audit / Certification Scheme Considered)

☐ Non Applicable (No prior audit)

List of prior audit reports taken into account in the preparation of the audit and/or for the grading of nonconformities (including "mock audits", "gap audits" or "pre-assessment audit")

Audit Date	Audit Report Reference	Audit Type
2021-10-11	615981	Surveillance 1
2020-07-14	615981	Stage 2
2020-06-14	615981	Stage 1

Summary of findings from prior audit listed above
There were no nonconformities reported during Surveillance 1.
There were four Grade 1 nonconformities and two Grade 3 nonconformities reported during Stage 2. All nonconformities were verified and closed 2021-10-14.
There were no nonconformities reported during Stage 1.

Section 9. Exclusions and Non-Applications of Requirements in the QMS

Exclusions:
None

Non-applicable:
7.5.3 Installation; Impladent does not install its devices
7.5.4 Servicing: Impladent does not service its devices
7.5.10 Customer Property; Impladent does not manage customer property or patient information.

Section 10. Outcome of Pre-Audit Activities (including Stage 1 as applicable)

☐ Check if documentation of Pre-Audit Activities is attached

Audit Codes:
ISO 13485
NACE: 51, 46, 28, 27; EAC: 17; Technical Area Codes: Simple: 17S; Complex: N/A

ISO 9001
Technical Area Codes: N/A

Auditor Codes Held:
Lead Auditor: Victor M. Hernandez; Technical Area Codes: MD1.2, MD6.1, MD7.6, MDS; Simple Codes: 17; Complex Codes: N/A

Surveillance:

I reviewed the audit documentation for the Surveillance 1 Assessment and there were no nonconformities reported. During Stage 2, there were four Grade 1 and two Grade 3, that were found to be completed.

I reviewed that an independent assessment of the regulatory registrations and listings in all five jurisdictions was completed and confirmed. Impladent is currently selling product in the US only.

I found that based on the review of the regulatory database: www.FDA.gov for MedWatch, Recalls, Warning Letters, search there were no reported post-market activities, such as adverse events and/or recalls within the last 12 months (review of www.FDA.gov for MedWatch, Recalls, Warning Letters, MAUDE database, Health Canada Recent health products recalls and alerts, Australia's TGA Recall Action Database, IMDRF International Medical Device Regulatory Forum Safety Information.

The company has not had any recalls, advisory notices, mdr, or vigilance.

I further verified that the certification scopes were reviewed as part of last EER audit. The scopes do still meet the requirements.

Section 11. Audit Findings

Section 11.1 - Process: Management

☐ Not audited

Completed Audit Tasks (check all that apply)

- ☐ 1. Quality Management System Planning
- ☐ 2. Management Representative
- ☐ 3. Quality Policy and Quality Objectives
- ☐ 4. Organizational Structure, Responsibility, Authority, Resources
- ☒ 5. Extent of Outsourcing
- ☐ 6. Personnel Competency & Training
- ☐ 7. Risk Management Planning and Review
- ☐ 8. Document Controls
- ☒ 9. Management Reviews
- ☒ 10. Distribution of Devices with Appropriate Marketing Authorization
- ☒ 11. Top Management Commitment to Quality

Description of the audited process or activity, and area (physical or organizational)

Major changes observed? ○ Yes ◉ No

Task 5 Extent of Outsourcing
Auditor: Victor M. Hernandez

I could determine the extent of outsourcing of processes through my review of the Supplier Assessment procedure MDSAP-1300, Rev. 1, that may affect the conformity of product with specified requirements.

I verified through review of the Supplier Assessment procedure MDSAP-1300, Rev. 1 and the Approved Vendor Classification Log MDSAP-1300-01, Rev. 1, that the proper documentation of controls in the quality management system. The manufacturer outsources the following processes: Production, Cleaning, Heat Treat, Material Testing, Sterile Packaging, Sterilization, Sterilization Validation, Labeling, and Laboratory Testing, to the subcontractors who have been verified as identified in Sec 7 and the list is current and accurate.

I verified that the company outsources approximately 64% of their process. The criticality (risk) of outsourced process and vendors was reviewed and found to be acceptable.

Australia (TGA):
I verified through review of the Quality Management System Manual MDSAP-QSM, Rev. 3, that as part of the conditions of marketing authorization (ARTG inclusion) require that Australian Sponsors have to undertake some regulatory activities including; customer complaint handling, the management and communication of technical files /technical documentation, adverse event reporting, conducting recalls, ensuring that the name and address of the Sponsor is provided with the device, the storage of devices, the keeping of complaint and distribution records, annual reporting for an initial period of three years, of specified information to the TGA for Class AIMD, Class III and Class IIb devices that are implantable, information about supply of specified IVDs, ensuring that some devices that would contravene Part 2 of the Poisons standards are not supplied.

I also verified that the manufacturer is not yet registered to sell product in Australia and thus, does not have a sponsor which provide services for the installation and servicing of a device on behalf of the Manufacturer and that if services are provided that the sponsor is treated as a supplier to the Manufacturer.

Canada (HC):
I verified through my review of the Quality Management System Manual MDSAP-QSM, Rev. 3, that the manufacturer is not yet registered to sell product in Canada and thus, the manufacturer does not yet utilize a regulatory correspondents, importers, distributors, or providers of a service.

I further verified through review of the Quality Management System Manual MDSAP-QSM, Rev. 3 and the Supplier Assessment procedure MDSAP-1300, Rev. 1, t, that the roles and responsibilities of any regulatory correspondents, importers, distributors, or providers of a service are required to be clearly documented in the organization's quality management system and are qualified as suppliers and controlled, as appropriate.

The information was gathered through my interview with Andrew Valen, President.
Clause and Regulation as applicable: ISO 13485:2016: 4.1.5, 4.2.1; TG (MD)R Sch3 P1 1.4(5) (b)(iii), (d)(ii); RDC ANVISA RDC ANVISA 665/2022: Art. 21, Art. 22, Art. 23, Art. 24; MHLW MO169: 5-, 6; FDA21 CFR 820.50]

Task 9 Management Reviews
Auditor: Victor M. Hernandez

I verified that procedures for management review process number: MDSAP-0100, Rev. 2 have been documented.

Management reviews are being conducted at planned intervals of once per year, and that they do include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements.

The following inputs; follow-up actions from previous management reviews; previous NB audit; applicable new or revised regulatory requirements; internal audits; corrective action; preventive action; risk management; complaint handling; customer feedback; returned goods; vendor assessment; calibration; training; monitoring and measurement of processes; monitoring and measurement of product; quality objectives; new/potential markets; reporting to regulatory authorities/regulatory concerns; changes that could affect the quality management system; and recommendations for improvement, were discussed in the management review and the review did meet the requirements of ISO 13485.

The following outputs; improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; improvement of product related to customer requirements; changes needed to respond to applicable new or revised regulatory requirements; and resource needs, were discussed as part of management review and the review did meet the requirements of ISO 13485. The following attendees: Andrew Valen, President; Maurice Valen, CEO; Zachary Adler, QMR, and Sharif King-Jones , Customer Service, were in the last management review and a quorum was achieved as defined in procedures. The last management review was held on 2022-07-01.

The information was gathered through my interview with Andrew Valen, President.
Clause and Regulations as applicable : ISO 13485:2016: 5.6, 5.6.1, 5.6.2, 5.6.3; TG(MD)R Sch3 P1 1.4(5)(b)(iii)(f); RDC ANVISA 665/2022: Art. 10, Art. 11, Art. 12; MHLW MO169: 18, 19, 20; FDA 21 CFR820.20(c)

Task 10 Distribution of Devices with Appropriate Marketing Authorization
Auditor: Victor M. Hernandez

I confirmed through my review of the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2 and the Volusion Software used for shipment, that the organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets.

I reviewed the following records; Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), to determine that devices have only been shipped to countries where the company had applicable licenses.

The information was gathered through my interview with Andrew Valen, President.
Clause and Regulations as applicable: ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3

Task 11 Top Management Commitment to Quality
Auditor: Victor M. Hernandez

I confirm that top management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and that the effectiveness of the system has been communicated to personnel.
Clause and Regulation: [ISO 13485:2016:4.1.1, 4.1.4, 5.1, 5.5.3; RDC ANVISA ANVISA 665/2022: Art. 4°, Art. 5°, Art. 6°, Art. 7°; MHLW MO169: 5-1, 5-4, 10, 17; FDA 21 CFR 820.20(a), 820.5]

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Supplier Assessment MDSAP-1300, Rev. 1
Inquiry and Order Processing MDSAP-0900, Rev. 2

Records Reviewed:
Approved Vendor Classification Log MDSAP-1300-01, Rev. 1
Management Review meeting minutes dated 2022-07-01
Order Processing Volusion Software

Invoice 76514 (USA)
Invoice 76546 (USA)
Invoice 76587 (USA)

Names and Titles of persons interviewed

Andrew Valen, President
Zachary Adler, Quality Management Rep
Maurice Valen, CEO

Nonconformity? (•) No ( ) Yes

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Management Processes that the process did conform to audit criteria. The processes were found to be effective.

Section 11.2 - Process: Device Marketing Authorization and Facility Registration

☐ Not audited

Completed Audit Tasks (check all that apply)

☐ 1. Submission for Device Marketing Authorization and Facility Registration

☒ 2. Evidence of Marketing Clearance or Approval

☒ 3. Notification of Changes to Marketed Devices or to the QMS

Description of the audited process or activity, and area (physical or organizational)
Task 2 Evidence of Marketing Clearance or Approval
Auditor: Victor M. Hernandez

Major changes observed? ○ Yes ◉ No

I confirmed through review of the FDA Establishment Registration & Device Listing 2431866 for Impladent, Ltd, that the organization has received appropriate marketing clearance or approval in the regulatory jurisdictions where the organization markets their devices. Currently, the manufacturer is only registered to sell product in the US.

Australia (TGA):
I verified that marketing authorization (inclusion in the Australian Register of Therapeutic Goods [ARTG]) has not been granted to the Australian Sponsor. The manufacturer is not yet registered to sell products in Australia, and thus the manufacturer does not have an Australian Sponsor. Nonetheless, the Medical Device Registration for Australia procedure MDSAP-4300, Rev. 1, defines the policy and practices employed by Impladent Ltd. to enter medical devices in Australia under the requirements of the Therapeutic Goods Medical Device Regulations.

I verified that the manufacturer is not yet registered to sell products in Australia, thus a Sponsor has not applied for marketing authorization since the Manufacturer has not completed a conformity assessment procedure that is relevant for the Class of the device. The manufacturer is not yet registered to sell products in Australia.

I verified that the Non-Australian Manufacturer has not assisted the Sponsor through the provision of information to support an application for marketing authorization and to meet the relevant conditions for on-going supply. The manufacturer is not yet registered to sell products in Australia.

I verified that the Sponsor has not been provided with a Certificate of Inclusion in the ARTG to identify the products that have been granted marketing authorization. The manufacturer is not yet registered to sell products in Australia.

I verified that the Sponsor has not imported, supplied, exported, or manufactured (in Australia) a medical device since the manufacturer is not yet registered to sell products in Australia. Nonetheless, the Medical Device Registration for Australia procedure MDSAP-4300, Rev. 1, provides requirements to comply with the essential principles. Since the manufacturer is not yet registered to sell products in Australia, the Manufacturer has not applied a relevant conformity assessment procedure, and the Sponsor has not included the device in the ARTG.

I confirmed through review of the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2 and the Volusion Software used for shipment, that the organization procedures do ensure that product is not released for supply to the Australian market since the Sponsor has not been issued with a "Certificate of Inclusion in the Australian Register of Therapeutic Goods", that identifies each kind of medical device that has been approved for supply to the Australian market [TG Act s41FJ], or the Sponsor holds a relevant exemption (TG Act Part 4-7).

I verified through review of the Medical Device Registration for Australia procedure MDSAP-4300, Rev. 1, that as part of an application for marketing authorization the Sponsor commits to certain requirements that are identified in s41FD - "Matters to be certified". These matters include establishing a written agreement with the manufacturer about the provision of information and establishing effective communication channels for post-market activities.

Canada (HC):
I verified through review of the Health Canada website, that the company has not imported or sold medical devices since the manufacturer of the device does not hold a license in respect of that device or, if the medical device has been subjected to a change described in section 34, an amended medical device license [CMDR 26]. The manufacturer is not yet registered to sell products in Canada.

United States (FDA):
21 CFR 807.81- Premarket Notification:

I verified through review of the Establishment Registration and Device Listing 2431866, that each person who is required to register his establishment pursuant to 807.20 has submitted a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:
(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.
(2) The device is being introduced into commercial distribution for the first time by a person required
to register 21 CFR 814 – Premarket Approval A Premarket approval is required for any FDA class III device that was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and
is not substantially equivalent to a device on the market before May 28, 1976, or to a device first
marketed on, or after that date, which has been classified into class I or class II.

I verified the company does not have any PMA products and is meeting their requirement.

I gathered the information through my interview with Andrew Valen, President.
Clause and regulation: [ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3

Task 3 Notification of Changes to Marketed Devices or to the QMS
Auditor: Victor M. Hernandez

I verified through review of the Quality System Document Control procedure MDSAP-1400, Rev. 2, that the organization is required to identify changes to marketed devices or the quality management system which require notification to regulatory authorities. The manufacturer is not yet registered to sell products in Australia.

I verified through my review of the change control process, that the manufacture has not made any of the above changes. The manufacturer is not yet registered to sell products in Australia.

Canada (HC):
I verified through review of the change control process, that the manufacturer has not made one or more changes and the manufacturer has not been required to submit to the Minister, in a format established by the Minister, an application for a medical device license amendment including the information and documents set out in section 32 that are relevant to the change [CMDR 34]. The manufacturer is not yet registered to sell products in Canada.

I confirmed through review of the Medical Device License for Heath Canada procedure MDSAP-4301, Rev. 1, that the manufacturer of a licensed medical device is required annually before November 1 and in a form authorized by the Minister, furnish the Minister with a statement signed by the manufacturer or by a person authorized to sign on the manufacturer's behalf describing any change to the information and documents supplied by the manufacturer with respect to the device, other than those to be submitted under section 34 or 43.1 [CMDR 43]. I verified the company has not made any changes since the previous audit. The manufacturer is not yet registered to sell products in Canada.

I verified through review of the Health Canada website, that the manufacturer is not the holder of a medical device license. The manufacturer is not yet registered to sell products in Canada.

I verified by reviewing the Medical Device License for Heath Canada procedure MDSAP-4301, Rev. 1, that the licensee is required to inform the Minister within 30 days after the discontinuance, to cancel the license at the time that the Minister is informed [CMDR 43(3)].

Subject to section 34, if a new or modified quality management system certificate is issued in respect of a licensed medical device, the manufacturer of the device shall submit a copy of the certificate to the Minister within 30 days after it is issued [CMDR 43.1].

I verified by reviewing the Medical Device License for Heath Canada procedure MDSAP-4301, Rev. 1, that the manufacturer procedure does meet the requirements specified for Canada.

I verified through my review of the change control process, that the manufacture has not made any of the above changes. The manufacturer is not yet registered to sell products in Canada.

I verified by reviewing the Medical Device License for Heath Canada procedure MDSAP-4301, Rev. 1, that if applicable the manufacturer has to notify the Minister of Health in Canada.

United States (FDA):
21 CFR 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices:
I verified through review of the Quality System Document Control procedure MDSAP-1400, Rev. 2, that the process requires update for the device listing information during each June and December or, at its discretion, at the time the change occurs.

The following were reviewed for changes that require updating and information to be submitted for each:
- Did the owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator
- Did the owner or operator discontinues commercial distribution of all devices in the same device class
- If updated registration if changes in individual ownership, corporate or partnership structure, or location of at the time of annual registration, or by letter if the changes occur at other times. Changes to be submitted within 30 days.
-If Changes in the names of officers and/or directors of the corporation(s) must be filed with the establishment's official correspondent and must be provided to the Food and Drug Administration upon receipt of a written request for this information

I verified that the company has not made any of the above changes that would require a notification to the regulatory authority. The manufacturer only sells Class 2 (510k) devices in the US.

I verified by reviewing the Quality System Document Control procedure MDSAP-1400, Rev. 2, for 21 CFR 807.81- Premarket Notification: that the company completes or will complete a new 510(k) application for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication. All changes in indications for use require the submission of a 510(k).
The following were reviewed for changes that require a 510(k) submission:
- Sterilization method
- Structural material
- Manufacturing method
- Operating parameters or conditions for use
- Patient or user safety features
- Sterile barrier packaging material
- Stability or expiration claims
- Design

I verified by reviewing the change control process, that the company has not made any of the above changes that would require a notification to the regulatory authority.

21 CFR 814.39 – PMA Supplements
I verified by reviewing the Quality System Document Control procedure MDSAP-1400, Rev. 2, that the company shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:
I reviewed the following items for changes:
(1) New indications for use of the device
(2) Labeling changes
(3) The use of a different facility or establishment to manufacture, process, or package the device
(4) Changes in sterilization procedures
(5) Changes in packaging
(6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device
(7) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA

I verified through my review of the Quality System Document Control procedure MDSAP-1400, Rev. 2, that the manufacturer procedure does meet the requirements specified for USA. The manufacturer only sells Class 2 (510k) devices in the US.

I verified that the company has not made changes to registered devices that would require a notification to the regulatory authority.

Since an applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness I verified reviewed if the company reported a change to the FDA in a post approval periodic reports required as a condition to approval of the device, (e.g., an editorial change in labeling which does not affect the safety or effectiveness of the device.) The manufacturer only sells Class 2 (510k) devices in the US.

I gathered the information through my interview with Andrew Valen, President.
Clause and regulation: ISO 13485:2016: 4.1.1, 4.2.1, 5.2, 7.2.1, 7.2.3, 7.3.9

Technical Documentations sampled and outcome of their evaluation ☐ Check if evaluation document attached

Tristar Bone Graft Fixation System K141764
Osteogen Sbrg K033098

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Medical Device Registration for Australia MDSAP-4300, Rev. 1
Inquiry and Order Processing MDSAP-0900, Rev. 2
Quality System Document Control MDSAP-1400, Rev. 2
Medical Device License for Heath Canada MDSAP-4301, Rev. 1

Records Reviewed:
FDA Establishment Registration & Device Listing 2431866
Order Processing Volusion Software

Names and Titles of persons interviewed

Andrew Valen, President
Zachary Adler, Quality Management Rep

Nonconformity? ◉ No ○ Yes

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Device Marketing Authorization and Facility Registration and that the process did conform to audit criteria. The processes were found to be effective.

Section 11.3 - Process: Measurement, Analysis and Improvement

☐ Not audited

Completed Audit Tasks (check all that apply)

- ☐ 1. Procedures for Measurement, Analysis, & Improvement of QMS Effectiveness and Product Conformity
- ☐ 2. Sources of Quality Data
- ☒ 3. Investigation of Nonconformity
- ☒ 4. Investigation of Potential Nonconformity
- ☒ 5. Correction, Corrective Action, and Preventive Action
- ☐ 6. Assessment of Design Change resulting from Corrective or Preventive Action
- ☐ 7. Assessment of Process Change resulting from Corrective or Preventive Action
- ☐ 8. Identification and Control of Nonconforming Product
- ☐ 9. Action Regarding Nonconforming Product Detected After Delivery
- ☒ 10. Internal Audit
- ☐ 11. Information Supplied for Management Review
- ☒ 12. Evaluation of Information from Post-Production Phase, Including Complaints
- ☒ 13. Communications with External Parties Involved on Complaints
- ☒ 14. Notification of Adverse Events
- ☒ 15. Notification of Advisory Notices
- ☒ 16. Top Management Commitment to Measurement, Analysis, and Improvement Process

Description of the audited process or activity, and area (physical or organizational)

Major changes observed? ○ Yes ◉ No

Task 3 Investigation of Nonconformity
Auditor: Victor M. Hernandez

(CA) I determined through my review of the Control of Nonconformities procedure MDSAP-1900, Rev. 2, that investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible.

I confirmed through review of the Nonconforming Material Report Log MDSAP-1900-04, Rev. 0 and NC-1-082721, that investigations are commensurate with the risk of the nonconformity.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 8.5.2; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f), TG(MD)R Sch1 P1 2; RDC ANVISA 665/2022: Art. 116, Art. 120 section II; MHLW MO169: 63; FDA 21 CFR 820.100 (a)(2)].

Task 4 Investigation of Potential Nonconformity
Auditor: Victor M. Hernandez

(PA) I determined through my review of the Control of Nonconformities procedure MDSAP-1900, Rev. 2, that investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible.

I confirmed through review of the only nonconformity reported since the previous assessment; NC-1-082721, that investigations are commensurate with the risk of the potential nonconformity.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation: ISO 13485:2016: 8.5.3; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f),TG(MD)R Sch1 P1 2; RDC ANVISA 665/2022: Art. 120 section I; MHLW MO169: 64; FDA 21 CFR 20.100(a)(2).

Task 5 Correction, Corrective Action, and Preventive Action
Auditor: Victor M. Hernandez

I confirmed through my review of the Corrective and Preventive Action procedure MDSAP-0500, Rev. 2, that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices.

I ensured after reviewing the Corrective and Preventive Action Request Log MDSAP-0500-02, Rev. 1 and CAPA-21, CAPA-22, CAPA-23, CAPA-24, and CAPA-25, that corrective action and preventive action is appropriate to the risk of the non-conformities or potential nonconformities encountered. The company has issued no corrective actions and I sampled none, which provides an adequate overview of the effectiveness of the corrective action process. The company has issued five preventive actions and I sampled all five, which provides an adequate overview of the effectiveness of the preventive action process.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation as applicable : ISO 13485:2016: 8.2.1, 8.2.5, 8.3.1,8.5.2, 8.5.3; TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)

(iii), (f);; RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 116, Art. 120 sections II, II, IV, V; MHLW MO169: 55-1, 57, 60-1, 63, 64; FDA 21 CFR 820.100(a)(3), 820.100 (a)(4),820.100(a)(6), 820.100(b).

Task 10 Internal Audit
Auditor: Victor M. Hernandez

I verified through review of the Internal Quality Audits procedure MDSAP 0300, Rev. 1, that internal audits of the quality management system are being conducted according to planned arrangements.

I verified by reviewing the Internal Quality Audits procedure MDSAP 0300, Rev. 1 and the Internal Audit Plan MDSAP-0300-01, Rev. 1, dated 2022-01-03, that the company does have an Internal audit schedule that covers the entire process and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system.

I confirmed through the following auditor training records; Sharif King-Jones and Zachary Adler that the internal audits do include provisions for auditor training and independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.

I reviewed the following audit records: 09292022-4, 09282022-1, 09092022-1, and 07072022-1, to verify applicable clauses of 13485:2016, and all applicable regulations were covered in the Internal audits. Internal audits occur on a quarterly basis throughout the year.

I gathered the information above through my interview with Andrew Valen, President.
Clause and Regulation as applicable : ISO 13485:2016: 6.2, 8.2.4; TG(MD)R Sch3 P1 1.4(5)(b)(iii); RDC ANVISA 1665/2022: Art. 122, Art. 123, Art. 124; MHLW MO169: 22, 23, 56; FDA 21 CFR 820.22, 820.100

Task 12 Evaluation of Information from Post-Production Phase, Including Complaints
Auditor: Victor M. Hernandez

I confirmed through review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, the Post Market Feedback System procedure MDSAP-3600, Rev. 0, the USA Recall procedure MDSAP-4400, Rev. 0, the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, and the Recall & Vigilance Medical Device Reporting Program for Europe procedure MDSAP-4402, Rev. 1, that the manufacturer has made effective arrangements for gaining experience from the - post-production phase, - handling complaints, and - investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process.

I verified that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.

I verified that the company had had five complaints; 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05 since the last assessment.

As part of my audit I sampled all five complaints which did represent the highest risk to the user or have the largest impact on the ability of the device to meet its essential design outputs.

Australia (TGA):
I verified through review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0 and the Post Market Feedback System procedure MDSAP-3600, Rev. 0, that the organization has procedures for a post-marketing system that includes a systematic review of post-production experience (e.g. from; expert user groups, customer surveys, customer complaints and warranty claims, service and repair information, literature reviews, post-production clinical trials, user feedback other than complaints, device tracking and registration schemes, user reactions during training, adverse event reports). As part of the audit, I verified that the company does have a proactive post market surveillance plan for devices manufactured.

The company has not had complaints and/or advisory notices in Australia. The manufacturer is not yet registered to sell product in Australia.

I reviewed the Post Market Feedback System procedure MDSAP-3600, Rev. 0, and found it contained proactive elements. Post Market Surveillance is documented on the Risk Management Review for Production and Post production Activities yearly report and also

presented during Management Review meetings.

Canada (HC):
I verified through review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, that the manufacturer is required to maintain records of reported problems related to the performance characteristics or safety of a device, including any consumer complaints received by the manufacturer after the device was first sold in Canada, and all actions taken by the manufacturer in response to the problems referred to in the complaints [CMDR Section 57]. Currently, the manufacturer is not registered to sell product in Canada.

I verified that the manufacturer has established and implemented documented procedures: Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, that will enable it to carry out an effective and timely investigation of the problems reports through the customer complaints, and to carry out an effective and timely recall of the device [CMDR Section 58].

The company has not had complaints and/or advisory notices in Canada. The manufacturer is not yet registered to sell product in Canada.

The company has not been required to file summary reports since the last audit. Currently, the manufacturer is not registered to sell product in Canada.

I verified by reviewing the Control of of Quality Records Retention procedure MDSAP-0200, Rev. 0, that the manufacturer has a procedure that does require record retention of the summary reports, the information used in the preparation of the reports, and any associated notification to the Minister for seven years after the day on which they are created. Currently, the manufacturer is not registered to sell product in Canada.

United States (FDA):
I verified through review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, that procedures have been defined, documented, and implemented for receiving, reviewing, and evaluating complaints by a formally designated unit.
The procedures do ensure that:
(1) All complaints are processed in a uniform and timely manner
(2) Oral complaints are documented upon receipt
(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA.

I found as part of my audit that the manufacturer had five complaints; 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05, in the US and I sampled all five, which formed a statistical sample to verify the complaint process does meet the regulation.

I verified through the review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, that the manufacturer does review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer does maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

I verified complaints of the failure of the device, labeling, or packaging to meet any of its specifications is reviewed, evaluated, and investigated, unless such investigation has already been made for a similar complaint and another investigation is not necessary.
I verified that any complaint that represents an event which must be reported to FDA must be promptly reviewed, evaluated, and investigated by a designated individual(s) and must be maintained in a separate portion of the complaint files or otherwise clearly identified. Records of investigation include a determination of:
(1) Whether the device failed to meet specifications
(2) Whether the device was being used for treatment or diagnosis
(3) The relationship, if any, of the device to the reported incident or adverse event
When an investigation is made, a record of the investigation is maintained by the formally designated unit.
The record of investigation must include:
(1) The name of the device
(2) The date the complaint was received
(3) Any unique identifier (UDI), or Universal Product Code(UPC) or any other device identification(s) and control number(s) used
(4) The name, address, and telephone number of the complainant
(5) The nature and details of the complaint
(6) The dates and results of investigation
(7) Any corrective action taken
When the manufacturer's formally designated unit is located at a site separate from the manufacturing establishment, the investigated

complaint(s) and the record(s) of investigation are reasonably accessible to the manufacturing establishment [21 CFR 820.198].

I verified this through review of the following complaint records; 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05. The records were found to be compliant and accessible

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 7.2.3, 7.5.4 (a), 8.2.1, 8.2.2, 8.5.1; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(3), 1.4(5)(b)(iii) &1.4(5)(f); RDC ANVISA 665/2022: Art. 121; CMDR 57-58, 61.4-61.6; MHLW MO169: 6, 29, 43, 55-1, 55-2, 62; FDA21 CFR 820.198]

Task 13 Communications with External Parties Involved on Complaints
Auditor: Victor M. Hernandez

I verified that through review of the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, that when an investigation determines that activities outside the organization contributed to a customer complaint, I verified that records show that relevant information was exchanged between the organizations involved.

The company has had complaints involving external parties.

This was verified through review of the following customer complaint records: 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.1.5, 7.4.1, 8.3.1; RDC ANVISA 1665/2022: Art. 120 section VI; MHLW MO169: 5-5, 37, 60-1; FDA21CFR 820.100(a)(6)

Task 14 Evaluation of Complaints for Adverse Event Reporting
Auditor: Victor M. Hernandez

I verify through review of the Post Market Feedback System procedure MDSAP-3600, Rev. 0 and the Medical Device Reporting procedure MDSAP-3100, Rev. 0, that the organization has defined and documented procedures for the evaluation of complaints for adverse event reporting.

I confirm adverse event reporting has not been needed to be performed through review of the following customer complaint records: 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05, and that decisions to not report complaints were made according to established procedures and a documented rationale.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1,7.2.3, 8.2.3; TG(MD)R Sch3 P1 1.4(3)(c); RDC ANVISA 665/2022: Art. 120 section VIII, RDC ANVISA 67/2009; CMDR 59-61.1; MHLW MO169: 6, 29, 55-3; FDA21 CFR 803

Task 15 Evaluation of Quality Problems for Advisory Notices
Auditor: Victor M. Hernandez

I confirmed through review of the USA Recall procedure MDSAP-4400, Rev. 0, the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, the Recall & Vigilance Medical Device Reporting Program for Europe procedure MDSAP-4402, Rev. 1, and Recall & Vigilance Medical Device Reporting Program for Australia procedure MDSAP-4403, Rev. 1, that the manufacturer has made effective arrangements for the timely evaluation of quality problems involving distributed product for potential issuance and implementation of advisory notices.

The company has not had any quality problems for potential issuance of advisory notices.

I confirmed that a review of quality problems were evaluated for potential issuance of advisory notices. The following customer complaint records: 2022-001, 2022-002, 2022-03, 2022-04, and 2022-05, were reviewed which also included decision to not report and I confirmed that the organization has taken actions appropriate based upon risk and the organization has documented the rational for the decision to report or not to report. The company has not filed advisory notices.

I gathered the information above through my interview with Andrew Valen, President.

Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 7.2.3, 8.3.3; TG(MD)R Sch3 P1 1.4(3)(c); RDC ANVISA 665/2022: Art. 120 section VIII, RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7°; CMDR 63-65.1; MHLW MO169: 5-3, 11, 54, 62; FDA 21 CFR 806

Task 16 Top Management Commitment to Measurement, Analysis, and Improvement Process
Auditor: Victor M. Hernandez

I determined, based on the assessment of the Measurement, Analysis and Improvement process overall, that management does provide the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system
Clause and regulation: ISO 13485:2016: 4.1.3, 5.2, 8.1, 8.5.1; RDC ANVISA 162013: 2.2.1; MHLW MO169: 5, 11, 54, 62

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Control of Nonconformities MDSAP-1900, Rev. 2
Corrective and Preventive Action MDSAP-0500, Rev. 2
Internal Quality Audits MDSAP 0300, Rev. 1
Customer Complaint Handling MDSAP-1700, Rev. 0
Post Market Feedback System MDSAP-3600, Rev. 0
USA Recall MDSAP-4400, Rev. 0
Recall & Vigilance Medical Device Reporting Program for Canada MDSAP-4401, Rev. 1
Recall & Vigilance Medical Device Reporting Program for Europe MDSAP-4402, Rev. 1
Control of Quality Records Retention MDSAP-0200, Rev. 0
Medical Device Reporting MDSAP-3100, Rev. 0

Records Reviewed:
Nonconforming Material Report Log MDSAP-1900-04, Rev. 0
NC-1-082721,
Corrective and Preventive Action Request Log MDSAP-0500-02, Rev. 1
CAPA-21
CAPA-22
CAPA-23
CAPA-24
CAPA-25
Internal Audit Plan MDSAP-0300-01, Rev. 1, dated 2022-01-03
Audit Report: 09292022-4
Audit Report: 09282022-1
Audit Report: 09092022-1
Audit Report: 07072022-1
Complaint: 2022-01
Complaint: 2022-02
Complaint: 2022-03
Complaint: 2022-04
Complaint: 2022-05

Names and Titles of persons interviewed

Andrew Valen, President
Zachary Adler, Quality Management Rep

Nonconformity? (•) No ( ) Yes

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Measurement Analysis and Improvement processes that the process did conform to audit criteria. The processes were found to be effective.

Section 11.4 - Process: Medical Device Adverse Events and Advisory Notices Reporting

☐ Not audited

Completed Audit Tasks (check all that apply)

☒ 1. Notification of Adverse Events ☒ 2. Notification of Advisory Notices

Description of the audited process or activity, and area (physical or organizational)
Task 1 Notification of Adverse Events
Auditor: Victor M. Hernandez

Major changes observed? ○ Yes ◉ No

I verified through review of the Post Market Feedback System procedure MDSAP-3600, Rev. 0 and the Medical Device Reporting procedure MDSAP-3100, Rev. 0, that the organization does have a process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities.

I verified that the complaint process does have a mechanism for reviewing each complaint to determine if a report to a regulatory authority is required.

I confirmed by reviewing the Customer Complaint Handling procedure MDSAP-1700, Rev. 0, the Post Market Feedback System procedure MDSAP-3600, Rev. 0, the USA Recall procedure MDSAP-4400, Rev. 0, the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, and the Recall & Vigilance Medical Device Reporting Program for Europe procedure MDSAP-4402, Rev. 1, that the organization's processes does meet the time frames required by each regulatory authority where the product is marketed.

Australia (TGA):
I verified through my review of the Post Market Feedback System procedure MDSAP-3600, Rev. 0, that the manufacture has implemented a post marketing system that includes the provision for adverse event reporting. Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(i).

I verified through review of the Recall & Vigilance Medical Device Reporting Program for Australia procedure MDSAP-4403, Rev. 1, that in the written agreement between Manufacturers and the Australian Sponsor [TG Act 41FD], events do have to be reported by the manufacturer to the TGA, or to the Sponsor in a timely manner to ensure that a Sponsor can meet their reporting obligations under the Therapeutic Goods (Medical Devices) Regulation 5.7 as follows:
-The manufacturer or other person becoming aware of an event that represents a serious threat to public health provided information as soon as practicable. The Sponsor is to report the event within 48 hours. This event has not occurred.
-The manufacturer or other person becoming aware of an event that led to the death or serious deterioration in the state of health of a patient, a user, or other person provided information as soon as practicable. The Sponsor is to report the event within 10 days. This event has not occurred.
-The manufacturer or other person becoming aware of an event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other provides information as soon as practicable. The Sponsor is to report the event within 30 days. This event has not occurred.

I verified that through review of Australia's TGA Recall Action Database, that Adverse events have not occurred since the previous audit. The manufacturer is not yet registered to sell products in Australia.

I verified through review of the Australian Register of Therapeutic Goods website, that the company has not included a device in the ARTG. The manufacturer is not yet registered to sell products in Australia.

The company does not distribute Class III and/or Implantable Class IIb products in Australia. The manufacturer is not yet registered to sell products in Australia.

Canada (HC):
Medical Device Regulations SOR/98-282, Section 59-61.1:
I verified through review of the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, that the manufacturer and the importer of a medical device have a process in place that defines the process for making a preliminary and final report to the minister concerning any incident occurring inside Canada involving a Class II-IV device device sold in Canada or a Class I device sold inside or outside Canada including the applicable reporting times for Canada. The manufacturer is not yet registered to sell products in Canada.

The company has not had any reportable incidents since the previous audit. The manufacturer is not yet registered to sell products in Canada.

The manufacturer has not had reportable incidents in Canada related to a. and b. below.
a. Related to the failure of the device or deterioration in its effectiveness or any inadequacy in its labeling or in its directions for use.
b. Has led to death or serious deterioration in the state of health of a patient, user, or other person, or could do so if it were to occur [CMDR 59]. The manufacturer is not yet registered to sell products in Canada.

I verified through review of the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, that the manufacturer is required to made effective arrangements to submit preliminary reports to the Minister if required and that the reports shall contain [CMDR 60 (2)]:
(a) the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) if the report is made by
(i) the manufacturer: the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or
(ii) the importer of the device: the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;
(c) the date on which the incident came to the attention of the manufacturer or importer;
(d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;
(e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;
(f) the identity of any other medical devices or accessories involved in the incident, if known;
(g) the manufacturer's or importer's preliminary comments with respect to the incident;
(h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and
(i) a statement indicating whether a previous report has been made to the Minister with respect to the device and, if so, the date of the report.
If a preliminary report required by section 60 is submitted to the Minister and /or Importer, I verified that the manufacturer will submit a final report to the Minister in writing in accordance with the timetable established under CMDR 60(2)(h) and the final report shall contain [CMDR 61(1)]:
(a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
(b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and
(c) any actions taken as a result of the investigation, which may include: (i) increased post-market surveillance of the device,
(ii) corrective and preventive action respecting the design and manufacture of the device, and
(iii) recall of the device.
If the reports required by section 60 and 61 are submitted to the Minister just by the Importer, I verified that the manufacturer has to advise the Minister in writing that the reports the manufacturer and importer will submit are identical and that the manufacturer has permitted the importer to prepare and submit reports to the Minister on the manufacturer's behalf [CMDR 61.1].

I verified that the Manufacturer of a medical device is required to submit to the Minister information regarding serious risk of injury to human health related to the safety of the device that it becomes aware of or receives, regarding:
(a) Risks that have been communicated by any Regulatory Agency that is set out in the List of Regulatory Agencies for the Purposes of Section 61.2 of the Medical Devices Regulations, or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a Regulatory Agency, and the manner of the communication;
(b) changes that have been made to the labelling of any medical device and that have been communicated to or requested by any Regulatory Agency that is set out in the list referred to in paragraph (a); and
(c) recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any Regulatory Agency that is set out in the list referred to in paragraph (a). [CMDR 61.2(2)]

I verified that manufacturers is required to submit notifications of foreign risks within 72 hours after receiving or becoming aware that a notifiable action has been taken in response to a serious risk, whichever comes first. [CMDR 61.2(3)]

United States (FDA):
21 CFR 803: Medical Device Reporting

I determined through review of the Medical Device Reporting procedure MDSAP-3100, Rev. 0, that the manufacturer has developed a process for reporting to FDA incidents involving device-related deaths, serious injuries, and reportable malfunctions that occur within and outside the United States if the same or similar device is marketed to the United States.

I confirmed through review of the Medical Device Reporting procedure MDSAP-3100, Rev. 0, that the manufacturer has developed, maintained, and implemented written medical device reporting (MDR) procedures for the following:
(a) Internal processes that provide for:
(1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
(2) A standardized review process or procedure for determining when an event meets the criteria for reporting; and
(3) Timely transmission of complete medical device reports to FDA
(b) Documentation and record keeping requirements for:
(1) Information that was evaluated to determine if an event was reportable;
(2) All medical device reports and information submitted to FDA
(3) Processes that ensure access to information that facilitates timely follow-up and audit.

I verified through review of www.FDA.gov for MedWatch, Recalls, Warning Letters, that the manufacturer has not had any incidents reportable to the US FDA.

I also verified that the process does require reports to be made within 30 calendar days after the day that the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that is marketed:
(1) May have caused or contributed to a death or serious injury; or
(2) Has malfunctioned and this device or a similar device that is marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

I confirmed through review of the Medical Device Reporting procedure MDSAP-3100, Rev. 0, that the manufacturer's MDR files will contain the following:
(1) Information (or references to information) related to the adverse event, including all documentation of deliberations and decision-making processes used to determine if a device related death, serious injury, or malfunction was or was not reportable to FDA.
(2) Copies of all MDR forms and other information related to the event submitted to FDA.

I gathered the information above through my interview with Andrew Valen, President.
Clause and regulation: ISO 13485:2016: 4.2.1, 7.2.3, 8.2.2, 8.2.3

Task 2 Notification of advisory notices
Auditor: Victor M. Hernandez

I verified by reviewing the USA Recall procedure MDSAP-4400, Rev. 0, the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, the Recall & Vigilance Medical Device Reporting Program for Europe procedure MDSAP-4402, Rev. 1, and Recall & Vigilance Medical Device Reporting Program for Australia procedure MDSAP-4403, Rev. 1, that the company does have a procedure for advisory notices and that advisory notices are required to be reported to regulatory authorities when necessary and comply with the time frames and record keeping requirements established by participating regulatory authorities.

The company has issued no advisory notices since the last audit.

Australia (TGA):
The company has issued no recalls in Australia since the last audit. The manufacturer is not yet registered to sell product in Australia.

I verified through review of the Post Market Feedback System procedure MDSAP-3600, Rev. 0 and the Recall & Vigilance Medical Device Reporting Program for Australia procedure MDSAP-4403, Rev. 1, that the manufacturer has implemented a post-marketing system that includes provisions for the recovery of devices – e.g. Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part 1 Clause 1.4(3)(c)(ii). I verified as part of the agreement between Manufacturers and the Australian Sponsor [TG Act 41FD] that proposed recalls are required to be reported by the manufacturer to the TGA, or to the Sponsor in a timely manner to ensure that a Sponsor can meet their reporting obligations. Therapeutic Goods (Medical Devices) Regulation 5.7, Therapeutic Goods Act Part 4-9 and the Uniform Recall Procedure for Therapeutic Goods (URPTG)].

The company has issued no recalls in Australia since the last audit. The manufacturer is not yet registered to sell product in Australia.

I further verified that the manufacturer is not yet registered to sell product in Australia, ant thus it does not have an Australian Sponsor. The Australian Sponsor will be required to provide manufacturers with information that will assist the manufacturer to comply with the obligations of a conformity assessment procedure (e.g. information in relation to the recovery of devices) [TG(MD)R Reg 5.8].

Canada (HC):
Medical Device Regulations SOR/98-282, Section 63 – 65.1:

The company has issued no recalls in Canada since the last audit.

I verified through review of the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, that the manufacturer and the importer of a medical device do have a procedure in place that did correctly define the process for recall in Canada.

I further verified through review of the Recall & Vigilance Medical Device Reporting Program for Canada procedure MDSAP-4401, Rev. 1, that on or before undertaking a recall of a device that the manufacturer will provide the minister with the following information [CMDR 64]:
(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;
(c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
(d) an evaluation of the risk associated with the defectiveness or possible defectiveness; (e) the number of affected units of the device that the manufacturer or importer
(i) manufactured in Canada,
(ii) imported into Canada, and
(iii) sold in Canada;
(f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;
(g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
(h) a copy of any communication issued with respect to the recall;
(i) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;
(j) the proposed action to prevent a recurrence of the problem; and
(k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.

United States (FDA):
21 CFR 806: Medical Devices; Reports of Corrections and Removals
The company has issued no recalls in the United States since the last audit.

I verified through review of the USA Recall procedure MDSAP-4400, Rev. 0, that the manufacturer does have a process in place to notify FDA in the event of actions concerning device corrections and removals and to maintain records of those corrections and removals.

I verified through review of www.FDA.gov for MedWatch, Recalls, Warning Letters, that the manufacturer has not implemented corrections and removals that would require notification to the US FDA.

I gathered the information above through my interview with Andrew Valen, President.
Clause No. ISO 13485:2016: 4.2.1, 7.2.3, 8.2.3, 8.3.3

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Post Market Feedback System MDSAP-3600, Rev. 0
Medical Device Reporting MDSAP-3100, Rev. 0

Customer Complaint Handling MDSAP-1700, Rev. 0
Post Market Feedback System procedure MDSAP-3600, Rev. 0
USA Recall MDSAP-4400, Rev. 0
Recall & Vigilance Medical Device Reporting Program for Canada MDSAP-4401, Rev. 1
Recall & Vigilance Medical Device Reporting Program for Europe MDSAP-4402, Rev. 1
Post Market Feedback System MDSAP-3600, Rev. 0
Recall & Vigilance Medical Device Reporting Program for Australia MDSAP-4403, Rev. 1

Records Reviewed:
Complaint: 2022-01
Complaint: 2022-02
Complaint: 2022-03
Complaint: 2022-04
Complaint: 2022-05

Names and Titles of persons interviewed

Andrew Valen, President
Zachary Adler, Quality Management Rep

Nonconformity? (•) **No** ( ) **Yes**

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Medical Device Adverse Event and Advisory Notice processes that the process did conform to audit criteria. The processes were found to be effective.

Section 11.5 - Process: Design and development

☒ Not audited

Section 11.6 - Process: Production and Service controls

☐ Not audited

Completed Audit Tasks (check all that apply)

- ☐ 1. Planning of Production and Service Process
- ☒ 2. Selection of Production and Service Process(es)
- ☒ 3. Controls for the Implementation of Selected Production and Service Process(es)
- ☒ 4. Control of Product Cleanliness
- ☐ 5. Infrastructure
- ☒ 6. Work Environment
- ☒ 7. Identification of Processes Subject to Validation
- ☒ 8. Process Validation
- ☒ 9. Validation of Sterilization Process
- ☒ 10. Monitoring and Measurement of Product Conformity
- ☒ 11. Control, Operation, and Monitoring of the Production and Service Process; Risk Controls
- ☒ 12. Competence of Personnel
- ☒ 13. Control of Monitoring and Measuring Device
- ☒ 14. Impact Analysis of Monitoring and Measuring Device Found Out of Specifications
- ☐ 15. Validation of Software Used for the Control of the Production and Service Process
- ☒ 16. "Device Master File"
- ☒ 17. Production Record; Evidence of Compliance of Released Devices
- ☒ 18. Traceability Applied to Implantable, Life-Supporting or Life-Sustaining Medical Devices
- ☐ 19. Identification of Product Status
- ☐ 20. Customer Property
- ☒ 21. Acceptance Activities
- ☒ 22. Identification, Control, and Disposition of Nonconforming Products
- ☒ 23. Rework of Nonconforming Products
- ☐ 24. Preservation of the Product
- ☒ 25. Review of Customer Requirements, Distribution Records
- ☐ 26. Installation Activities
- ☐ 27. Servicing Activities
- ☐ 28. Risk Controls Applied to Transport, Installation, and Servicing
- ☒ 29. Top Management Commitment to the Production and Service Process

Description of the audited process or activity, and area (physical or organizational)

Major changes observed? ○ Yes ◉ No

Task 2 Selection of production and service process(es)
Auditor: Victor M. Hernandez

I reviewed the following production processes; Filling Vials for the OsteoGen Synthetic Non-Ceramic Hydroxylapatite Osteoconductive Implant Material (K843398), considering the following primary criteria; Use of production processes that directly impact the ability of the device to meet its Essential Design Outputs.

Task 3 Controls for the implementation of selected production and service process(es)
Auditor: Victor M. Hernandez

I determined through review of the Quality Management System Manual MDSAP-QSM, Rev. 3, that the production and service process is planned and conducted under controlled conditions that include the following:• information describing product characteristics• documented procedures, requirements, work instructions, and reference materials, reference measurements, and criteria for workmanship• suitable equipment• monitoring and measuring devices• the implementation of monitoring and measurement of process parameters and product characteristics during production• the implementation of release, delivery and post-delivery activities• the implementation of defined operations for labeling and packaging• the establishment of documented requirements for changes to methods and processes.

I reviewed the following device master records (technical files); MDSAP-2800-01, Rev. 3, to verify the above information is correct.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable:: [ISO 13485:2016: 7.5.1, 8.2.5, 8.2.6; TG(MD)R Sch3 P1 Cl1.4(5)(d)&(e); RDC ANVISA 1665/2022: Art. 30, Art. 63, Art. 62, Art. 64, Art. 65, Art. 66, Art. 84, Art. 88; MHLW MO169: 40, 57, 58, 59; 21 CFR 820.70(a), 820.70(b), 820.75, 820.120, 820.130]

Task 4 Control of product cleanliness
Auditor: Victor M. Hernandez

I determined through review of the Cleaning procedure MDSAP-2900, Rev. 0, that the organization has established documented requirements for workstation, customer service, labeling, processing, storage, and quarantine areas cleaning. In addition, Environmental Controls are established in the Environmental Control procedure MDSAP-3200, Rev. 0. Product is not cleaned prior to sterilization, product is provided sterile.

I confirmed through review of the Cleaning procedure MDSAP-2900, Rev. 0, that Cleaning and Pest Control Services are handled by the building landlord and are written into the lease agreement.

A pest control program has been established and where chemicals are used as part of the pest control program, the company has ensured that the chemical used do not affect product quality. The pest control company is Wipeout Exterminating. Pest control is completed on a monthly basis. The following chemicals are used; InVict Granular Bair and Firststrike Soft Bait.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 4.2.3, 6.4.2, 7.5.2; TG(MD)R Sch3 P1 Cl1.4(5)(d); RDC ANVISA 665/2022: Art. 69, Art. 75, Art. 79; MHLW MO169: 6, 25, 41; 21 CFR 820.70(c), 820.70(d), 820.70(e), 820.70(h)

Task 6 Work Environment
Auditor: Victor M. Hernandez

I verified through my review of the Cleaning procedure MDSAP-2900, Rev. 0 and the Environmental Control procedure MDSAP-3200, Rev. 0, that documented requirements have been established, implemented and maintained for:• health, cleanliness, and clothing of personnel that could have an adverse effect on product quality• monitoring and controlling work environment conditions that can have an adverse effect on product quality• training or supervision of personnel who are required to work under special environmental conditions• controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel.

The company does not operate clean rooms. The company has a gowning procedure for the Vials Filling area; Gowning and Cleaning Verification for Filling of OsteoGen procedure MDSAP-6001, Rev. 4, and does provide proper gowning processes. The following training records were reviewed for gowning and found to have been completed; Sharif King-Jones, Zach Adler, and Andrew Valen.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 6.4, 6.4.1; TG(MD)R Sch1 P2 7.2, 8; RDC ANVISA 665/2022: Art. 68: 5.1.3; MHLW MO169: 6, 25-1, 25-2;21 CFR 820.70(c), 820.70(d), 820.70(e)]

Task 7 Identification of processes subject to validation
Auditor: Victor M. Hernandez

I determined through review of the Powder Filler Unit Qualification SN1 Protocol/Report IMP-001, Rev. 0, the FillPro Edge Software Qualification Protocol/Report Project 7001A, dated 2017-10-06, and the IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer, that the selected process; Filling Vials and Dry Heat Sterilization, including outsourced processes have been reviewed to determine if validation of the processes is required.

The manufacturer does manufacture devices that have the following processes completed: sterilization and/or other processes requiring validation.

United States (FDA):
I verified that the manufacturer does complete processes that require validation including but not limited to sterilization.

I verified that the manufacturer has completed process validation for Dry Heat Sterilization 21 CFR820.75; preamble comment 143. This was verified through review of the IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer dated 2020-07-23.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 4.1.6, 7.5.6; TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d), RDC ANVISA 665/2022: Art. 103, Art. 104, Art. 105, Art. 106; MHLW MO169: 6, 5-6, 45; 21 CFR 820.75(a)].

Task 8 Process validation
Auditor: Victor M. Hernandez

I verified that the selected processes: Filling Vials for the OsteoGen Synthetic Non-Ceramic Hydroxylapatite Osteoconductive Implant Material (K843398) and Dry Heat Sterilization, do require validation since the resulting output cannot be fully verified.

The following devices require validation based the processes that must be validated: Tristar Bone Graft Fixation System, Osteotape, and Osteogen.

The processes have been validated according to the Process Validation procedure MDSAP-3300, Rev. 1.

I confirmed that the validation does demonstrate the ability of the process/es to consistently achieve the planned result.

Since the previous audit, the manufacturer has not made changes that could impact a previously reviewed/validated processes.

The manufacturer does not manufacture devices that are cleaned before sale or sterilization.

The manufacturer does manufacture devices that are sold non sterile but are intended to be sterilized prior to use. Sterilization Instructions are provided in the Tristar IFU, Rev. A.

The following device; Tristar Bone Graft Fixation System are sold non sterile but intended to be sterilized by the end user who processes the sterilization cycle of Moist Heat method. Instructions for sterilization are provided from the manufacturer to the end user. Sterilization Instructions are provided in the Tristar IFU, Rev. A.

Australia (TGA):
I confirmed that methods of validation have regard to the generally acknowledged state of the art (e.g. current Medical Device Standard Orders - MDSO, ISO/IEC Standards, BP, EP, USP etc.) [TG Act s41CB, TG(MD)R Sch 1 P1 2(1)].

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 7.5.6; TG(MD)R Sch1 P1 2(1), Sch3 P1 1.4(5)(d); RDC ANVISA 665/2022: Art. 3° section 31, Art. 103; MHLW MO169: 6, 45; 21 CFR 820.75(a), 820.75(c)]

Task 9 Validation of Sterilization Process
Auditor: Victor M. Hernandez

I verified through review of DMR; MDSAP-2800-01, Rev. 3, that the manufacturer does manufacture devices that will be sterilized by the manufacturer or the end user.

I verified through review of the IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer dated 2020-07-23, that the sterilization process is validated, periodically re-validated, and records of the validation are available

I verified the manufacturer utilizes harmonized standards for sterile validation. I verified the manufacturer utilizes the ISO 20857:2010 standard for sterilization validation.

Dry Heat
I verified through review of the IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer dated 2020-07-23, that the process is validated.

I also reviewed the Dry Heat Sterilization procedure MDSAP-5004, Rev. 4, and could confirm the company has completed ongoing monitoring of the process. Dry Heat processing records; Sterile Lot Number H0703B were reviewed and found to have met the process as specified in the validation. The manufacturer only sterilizes a batch of product 1-2 per year.

I verified that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions.

I determine through review of the above processing sheets that the sterilization process and results are documented and are traceable to each batch of product.

Australia (TGA):
I verified that methods of sterilization validation have regard to the generally acknowledged state of the art. (eAustralian Medical Device Standard Orders – MDSO e.g. Medical Device Standards Order (Endotoxin Requirements for Medical Devices) 2018) or Australian Conformity Assessment Standard Orders - Conformity Assessment Standards Order (Quality Management Systems) 2019 that refer to the use of ISO 11135, ISO 11137 and other standards.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 7.5.5, 7.5.6, 7.5.7; TG(MD)R Sch1 2(1) & 8.3, Sch3 P1 1.4(5)(d); RDC ANVISA

665/2022: Art. 83, Art. 103, Art. 104, Art. 105, Art. 106; CMDR 17; MHLW MO169: 6, 44, 45, 46; 21 CFR 820.75, 820.184(d).

Task 10 Monitoring and measurement of product conformity
Auditor: Victor M. Hernandez

I verified through review of the Receipt, Inspection, Labeling, and Inventory Control of OsteoGen Particulates procedure MDSAP-2203, Rev. 3, that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements.

I reviewed the following records: Receipt and Check-in of Filling Supplies MDSAP-5002, Rev. 5; Filling Vials MDSAP-5003, Rev. 4; Sterility Test and Biennial Bioburden Testing MDSAP-5005, Rev. 4 for Production Lot H0703B, to verify that the product does meet specifications.

I confirmed through review of the Risk Management procedure MDSAP-0400, Rev. 1 and the Risk Assessment for the Powder Filler process under IMP-001, Rev. 0, that product risk is considered in the type and extent of product monitoring activities.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.6; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e); RDC ANVISA 665/2022: Art. 18, Art. 19, Art. 20, Art. 64, Art. 131; MHLW MO169: 26, 40, 54, 58, 59; 21 CFR 820.70(a), 820.250(a)

Task 11 Control, operation, and monitoring of the production and service process; risk controls
Auditor: Victor M. Hernandez

I verified through review of the following process validations: Powder Filler Unit Qualification SN1 Protocol/Report IMP-001, Rev. 0, the FillPro Edge Software Qualification Protocol/Report Project 7001A, dated 2017-10-06, and the IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer, that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records.

I verified through review of the Risk Management procedure MDSAP-0400, Rev. 1 and the Risk Assessment for the Powder Filler process under IMP-001, Rev. 0, that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.1, 7.5.1, 8.1, 8.2.5; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e); RDC ANVISA 1665/2022: Art. 18, Art. 19, Art. 20, Art. 64, Art. 83, Art. 128, Art. 131; MHLW MO169: 26, 40, 54, 57; 21 CFR 820.70(a), 820.75(b), 820.250

Australia
The technical documentation does contain, or reference, evidence of compliance with the Essential Principles and the following minimum requirements:
- A detailed description of the product, including the intended use, intended user, risk classification and assigned Global Medical Device Nomenclature (GMDN) code. For IVD medical devices, the description should also include specimen types, a list of kit components, methodology and any instrumentation to be used
- the inclusion of information gathered in feedback processes (e.g. complaints, adverse event reporting or recalls for product correction) as a potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes
- an index of the compilation of documents, or if documentation is not collated, a reference to the relevant documentation
- a risk management file (e.g. select a particular risk and confirm that it has been managed in accordance with the requirements of ISO 14971)
- selected report(s) of pre-clinical data and/or bench testing (including studies in animal models, testing to support compliance with relevant standards, technical performance and safety tests for electrical safety, mechanical safety, radiation safety etc.) identified by the Manufacturer as evidence of compliance with relevant Essential Principles
- a selected clinical evaluation report to confirm that it is current and was prepared by an appropriately qualified expert
- any other documentation required for the type of device (e.g.- special requirements for devices incorporating medicinal substances or materials of animal origin);
- the information that accompanies a device (labelling, instructions for use, patient implant cards and leaflets)
- the declaration of conformity (may be in draft form)
The manufacturer is not yet registered to sell products in Australia.

Task 12 Competence of personnel
Auditor: Victor M. Hernandez

I verified through review of the following job descriptions; President (0700-02-02); Director HR (0700-02-03); Director Operations (0700-02-04), and Director Quality (0700-02-12), that competency requirements have been established.

I also verified through review of the following CVs: Zachary Adler, QMR; Sharif King-Jones, Customer Service; and Lyman Tsang, Customer Service; that the person hired for the position did meet the requirements of the job description.

I further verified through review of the Training and Skills Appraisal procedure MDSAP-0800, Rev. 1, and Job Descriptions; (0700-02-02); (0700-02-03); (0700-02-04), and (0700-02-12), that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization. I reviewed the following training records; Zachary Adler, QMR; Sharif King-Jones, Customer Service; and Lyman Tsang, Customer Service; to ensure that training is provided.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 6.2; RDC ANVISA MO169: 26, 40, 54, 57 MHLW MO169: 22; 21 CFR 820.25, 820.70(d), 820.75(b).

Task 13 Control of monitoring and measuring device
Auditor: Victor M. Hernandez

I confirmed through review of the Calibration of Inspection, Measuring & Test Equipment procedure MDSAP-2300, Rev. 2, that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements.

I verified through review of the following records; Calibration Certificate-220531346; Calibration Certificate-4135-12782741; Calibration Certificate-4648-12618006; Calibration Certificate-192026L1; Calibration Certificate-1383976; and Calibration Certificate-1384590, that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.5.1, 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 665/2022: Art. 93, Art. 94, Art. 95; MHLW MO169: 40, 53; 21 CFR 820.70(g), 820.72.

Task 14 Impact analysis of monitoring and measuring device found out of specifications
Auditor: Victor M. Hernandez

I verified by review of calibration records that the company has not had equipment that was identified as out of calibration as found.

I verified through review of the Calibration of Inspection, Measuring & Test Equipment procedure MDSAP-2300, Rev. 2, Calibration Certificate-220531346; Calibration Certificate-4135-12782741; Calibration Certificate-4648-12618006; Calibration Certificate-192026L1; Calibration Certificate-1383976; and Calibration Certificate-1384590, that the control of the monitoring and measuring devices is adequate to ensure valid results.

I confirmed through review of the Filling Room that monitoring and measuring devices are protected from damage or deterioration.

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 1665/2022: Art. 102; MHLW MO169: 53; 21 CFR 820.72(a)

Task 16 Device master file
Auditor: Victor M. Hernandez

I determined by my review of DMR; MDSAP-2800-01, Rev. 3, that the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications and when applicable, requirements for installation and servicing.

I also confirmed through review of the Identification and Traceability procedure MDSAP-4600, Rev. 0 and manufacturing records for OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that the manufacturer has determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.

Australia (TGA):
I verified by review of the product labels for OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that the design and location of information to be provided with a medical device, including labelling and instructions for use, do comply with Essential Principle 13 and implant cards and leaflets with Essential principle 13A. The manufacturer is not yet registered to sell product in Australia.

Canada (HC):
I verified through review of the Risk Management procedure MDSAP-0400, Rev. 1 and the Risk Assessment for the Powder Filler process under IMP-001, Rev. 0, that the manufacturer does maintain objective evidence that devices meet the safety and effectiveness requirements of the CMDR [CMDR 9(2)]. The manufacturer is not yet registered to sell product in Canada.

I verified through review of the Medical Device License for Health Canada procedure MDSAP-4301, Rev. 1, that devices sold in Canada have labeling that does conform to Canadian English and French language requirements and contain the manufacturer's name and address, device identifier, control number (for Class III and IV devices), contents of packaging, sterility, expiry, intended use, directions for use and any special storage conditions [CMDR 21-23]. The manufacturer is not yet registered to sell product in Canada.

I verified through review of Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that the manufacturer maintains distribution records in respect of a device that will permit a complete and rapid withdrawal of the device from the market [CMDR 52-56]. The manufacturer is not yet registered to sell product in Canada.

United States (FDA):
I verified through review of OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that a control number is required for traceability and confirm that such control number is on or accompanies the device throughout distribution [21 CFR 820.120(e)].

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 4.2.3, 7.1, 7.5.8, 7.5.9.1; TG(MD)R Sch3 P1 1.4(5) (c),(d),(e) & 1.9; RDC ANVISA 1665/2022: Art. 18, Art. 19, Art. 20, Art. 63, Art. 64, Art. 84, Art. 85, Art. 86, Art. 87 CMDR 9(2), 21-23, 52-56, 66-68; MHLW MO169: 6, 7-2, 26, 47, 48; 21 CFR 820.65, 820.181.

Task 17 Production record; evidence of compliance of released devices
Auditor: Victor M. Hernandez

I determined by reviewing the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2, Batch Records OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; Invoice 76514 (USA); Invoice 76546 (USA); and Invoice 76587 (USA); that the manufacturer has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in task 16, and the requirements for product release were met and documented.

United States (FDA):
I verified by reviewing the Labeling and Packaging Control procedure MDSAP-2700, Rev. 0, that labeling is not released for storage or use until a designated individual has examined the labeling for accuracy including, where applicable, the correct unique device identifier (UDI) or Universal Product Code (UPC), expiration date, control number, storage instructions, handling instructions, and any additional processing instructions [21 CFR 820.120(b)]. Due to the fact that the company manufactures 1-2 lots of product per year, and labels are printed as needed, there were no labels available for review other than the ones on finished product.

I confirmed through review of label storage in the Company President's office, that labeling is stored in a manner that provides proper identification and prevents mix-ups.

I verified by reviewing the Labeling and Packaging Control procedure MDSAP-2700, Rev. 0 and the manufacturing area, that labeling and packaging operations are controlled to prevent labeling mix-ups [21 CFR 820.120(c) and (d)].

I verified by reviewing the following Batch Records: OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that the label

and labeling used for each production unit, lot, or batch are documented in the batch record, as well as any control numbers used [21 CFR 820.120(e), 820.184(e)].

I verified the above information through my interview with Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 7.5.1, 7.5.8, 7.5.9.1, 8.2.6; RDC ANVISA 665/2022: Art. 39, Art. 113, Art. 114; MHLW MO169: 6, 40, 47, 48, 58, 59; 21 CFR 820.120, 820.184].

Task 18 Traceability applied to implantable, life-supporting or life-sustaining medical devices
Auditor: Victor M. Hernandez

I verified through review of the Tristar Bone Graft Fixation System K141764 and the Osteogen Sbrg K033098 products, that the company does manufacture nonactive implantable medical devices.

Since the organization manufactures nonactive implantable medical devices, I confirmed through my review of the Identification and Traceability procedure MDSAP-4600, Rev. 0, and Batch Records: OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that the manufacturer does maintain traceability records of all components, materials, and work environment conditions (if these could cause the medical device to not satisfy its specified requirements) in addition to records of the identity of personnel performing any inspection or testing of these devices.

The company does utilize agents or distributors for their products.

I confirmed through review of the following agreements: Ultradent Products, Inc. dated 2021-06-24 and Dentall, Inc. dated 2021-05-03, that the organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection. I verified through my review of Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that the organization does record the name and address of shipping consignees for these devices.

Canada (HC):
I verified the manufacturer does manufacture devices that are Schedule 2 in Canada.
I verified through my review of the Labeling and Packaging Control procedure MDSAP-2700, Rev. 0, that the manufacturer has identified Schedule 2 implants and provides implant registration cards with devices or employs another suitable system approved by Health Canada [CMDR 66-68]. The manufacturer is not yet registered to sell product in Canada.

I also verified through my review of the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2, that the manufacturer of devices that are listed on Schedule 2 of the Medical Devices Regulations is required to maintain distribution records of these devices as well as any information received on implant registration cards related to these Schedule 2 devices [CMDR 54].

United States (FDA):
I verified the manufacturer does not manufacture devices that has received a tracking order from FDA.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: [ISO 13485:2016: 4.2.1, 7.5.9.2, 8.2.6; MHLW MO169: 6, 49, 59; 21 CFR 820.65].

Task 21 Acceptance activities
Auditor: Victor M. Hernandez

I verified through review of the Receipt, Inspection, Labeling and Inventory Control of OsteoGen Particulates procedure MDSAP-2203, Rev. 3, that acceptance activities assure conformity with specifications and are documented.

I further confirmed through review of Batch Records: OPL1020-5, Lot 2214; OPL1020-5, Lot 2225; and OPL1020-5, Lot 2224; that the extent of acceptance activities is commensurate with the risk posed by the device.

United States (FDA):
I verified through review of the Statistical Techniques procedure MDSAP-2600, Rev. 0, that the manufacturer has established and maintained procedures to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed [21CFR 820.250(b)].

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 7.4.3, 7.5.8, 8.2.6; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d); RDC ANVISA 665/2022: Art. 88, Art. 89, Art. 90, Art. 131; MHLW MO169: 6, 39, 47,58, 59; 21 CFR 820.80, 820.250(b).

Task 22 Identification, control, and disposition of nonconforming products
Auditor: Victor M. Hernandez

I verified through review of the Control of Nonconformities procedure MDSAP-1900, Rev. 2 and the Nonconforming Product/Failure Investigation procedure MDSAP-2100, Rev. 0, that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.

I reviewed the following nonconforming product records for review and disposition: NC-1-082721. There has only been one nonconforming product report issued since the previous assessment for damage during shipment. The disposition was to use the product for Demo purposes.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.5.8, 8.3; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(b); RDC ANVISA 665/2022: Art. 115, Art. 116 MHLW MO169: 47, 60-1, 60-2, 60-3, 60-4;; 21 CFR 820.60, 820.90(a), 820.86, 820.100(a).

Task 23 Rework of nonconforming products
Auditor: Victor M. Hernandez

I verified through review of section 8.3.4 of the Quality Management System Manual MDSAP-QSM, Rev. 3, that the company can rework product.

I verified through review of the Nonconforming Material Report Log MDSAP-1900-04, Rev. 0 and NC-1-082721, that the company has not reworked any products since the last audit.

I verified the above information through my interview of Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 8.3.4; RDC ANVISA 665/2022: Art. 119; MO169: 60-4; MHLW MO169: 60-4; 21 CFR 820.90(b).

Task 25 Review of customer requirements, distribution records
Auditor: Victor M. Hernandez

I confirmed through review of the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2, that the organization does perform a review of the customer's requirements, including the purchase order requirements, prior to the organization's commitment to supply a product to a customer.

I further verified through review of the following records: Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that the organization does maintain documentation required by regulatory authorities regarding maintenance of distribution records.

Canada (HC):
I verified by reviewing the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2, Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that the manufacturer does maintain distribution records that contain sufficient information to permit complete and rapid withdrawal of the medical device from the market [CMDR 52-53]. The manufacturer is not yet registered to sell products in Canada.

I verified through review of the Control of Quality Records Retention procedure MDSAP-0200, Rev. 0 and the following distribution records: Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that distribution records of a device are retained by the manufacturer in a manner that will allow for timely retrieval, for the longer of (a) the projected useful life of the device; and (b) two years after the date the device was shipped [CMDR 55-56]. The manufacturer is not yet registered to sell products in Canada.

United States (FDA):
I verified through review of the Inquiry and Order Processing procedure MDSAP-0900, Rev. 2, Invoice 76514 (USA), Invoice 76546 (USA), and Invoice 76587 (USA), that the manufacturer does maintain distribution records which include or refer to the location of the name and

address of the initial consignee, the identification and quantity of devices shipped; and any control numbers used [21 CFR 820.160(b)].

I verified the above through my interview with Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 4.2.1, 5.2, 7.2.2, 7.5.9; RDC ANVISA 665/2022: Art. 112; MHLW MO169: 6, 11, 28, 48, 49; 21 CFR 820.160(a).

Task 29 Top management commitment to the production and service process
Auditor: Victor M. Hernandez

I determined, based on the assessment of the production and service control process overall, that management does provide the necessary commitment to the production and service control process to ensure devices meet specified requirements and quality objectives.

Clause and regulation: ISO 13485:2016: 5.1, 5.2; RDC ANVISA 665/2022: Art. 5°, Art. 6°, Art. 7° MHLW MO169: 10, 11

Selected Production and Service Processes and Rationale for their Selection

I reviewed the Filling Vials process for the OsteoGen Synthetic Non-Ceramic Hydroxylapatite Osteoconductive Implant Material (K843398), considering the following primary criteria; Use of production processes that directly impact the ability of the device to meet its Essential Design Outputs.

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Cleaning MDSAP-2900, Rev. 0
Environmental Control MDSAP-3200, Rev. 0
Gowning and Cleaning Verification for Filling of OsteoGen MDSAP-6001, Rev. 4
Process Validation MDSAP-3300, Rev. 1
Dry Heat Sterilization MDSAP-5004, Rev. 4
Receipt, Inspection, Labeling, and Inventory Control of OsteoGen Particulates MDSAP-2203, Rev. 3,
Risk Management MDSAP-0400, Rev. 1
Training and Skills Appraisal MDSAP-0800, Rev. 1
Calibration of Inspection, Measuring & Test Equipment MDSAP-2300, Rev. 2
Identification and Traceability MDSAP-4600, Rev. 0
Medical Device License for Health Canada MDSAP-4301, Rev. 1
Inquiry and Order Processing MDSAP-0900, Rev. 2
Labeling and Packaging Control MDSAP-2700, Rev. 0
Statistical Techniques MDSAP-2600, Rev. 0
Control of Nonconformities MDSAP-1900, Rev. 2
Nonconforming Product/Failure Investigation MDSAP-2100, Rev. 0
Control of Quality Records Retention MDSAP-0200, Rev. 0

Records Reviewed:
OsteoGen Technical File; MDSAP-2800-01, Rev. 3
Monthly Pest Control Records
Powder Filler Unit Qualification SN1 Protocol/Report IMP-001, Rev. 0
FillPro Edge Software Qualification Protocol/Report Project 7001A, dated 2017-10-06
IQ/OQ/PQ for the Yamato DKN602 Dry Heat Sterilizer dated 2020-07-23
Sterile Lot Number H0703B
Receipt and Check-in of Filling Supplies MDSAP-5002, Rev. 5
Filling Vials MDSAP-5003, Rev. 4
Sterility Test and Biennial Bioburden Testing MDSAP-5005, Rev. 4
Risk Assessment for the Powder Filler process under IMP-001, Rev. 0
Job Description for; President (0700-02-02)
Job Description for; Director HR (0700-02-03)
Job Description for; Director Operations (0700-02-04)
Job Description for; Director Quality (0700-02-12)
CV for: Zachary Adler, QMR

CV for: Sharif King-Jones, Customer Service
CV for: Lyman Tsang, Customer Service
Calibration Certificate-220531346
Calibration Certificate-4135-12782741
Calibration Certificate-4648-12618006
Calibration Certificate-192026L1
Calibration Certificate-1383976
Calibration Certificate-1384590
DMR; MDSAP-2800-01, Rev. 3
OPL1020-5, Lot 2214
OPL1020-5, Lot 2225
OPL1020-5, Lot 2224
Invoice 76514 (USA)
Invoice 76546 (USA)
Invoice 76587 (USA)
Tristar Bone Graft Fixation System (510k) K141764
Osteogen Sbrg (510k) K033098
Supplier Agreement with: Ultradent Products, Inc. dated 2021-06-24
Supplier Agreement with: Dentall, Inc. dated 2021-05-03
Nonconforming Material Report Log MDSAP-1900-04, Rev. 0
NC-1-082721

Names and Titles of persons interviewed

Andrew Valen, President
Zachary Adler, Quality Management Rep

Nonconformity? (•) **No** ( ) **Yes**

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Production processes that the process did conform to audit criteria. The processes were found to be effective.

Section 11.7 - Process: Purchasing

☐ Not audited

Completed Audit Tasks (check all that apply)

- ☐ 1. Planning Activities Regarding Purchased Products and Outsourced Processes
- ☐ 2. Selection of Supplier File to Audit
- ☐ 3. Procedure for the Control of Purchased Products and Outsourced Processes
- ☐ 4. Extent of Controls Applied to the Supplier and the Purchased Product; Criteria for Selection, Evaluation, and Re-evaluation of the Supplier
- ☐ 5. Selection of Supplier Based on Ability of the Supplier to Satisfy the Specified Purchase Requirements
- ☒ 6. Records of Supplier Evaluation
- ☐ 7. Effective Controls over Supplier and Products
- ☐ 8. Verification of the Adequacy of Purchasing Information, Specified Purchase Requirements, and Written Agreement to Notify Changes, before their Communication to the Supplier.
- ☐ 9. Documented Purchasing Information and Specified Purchase Requirements.
- ☐ 10. Verification of Purchased Products
- ☒ 11. Purchasing Control Activities as Source of Quality Data for the Measurement, Analysis, and Improvement Process
- ☐ 12. Top Management Commitment to the Purchasing Process

Description of the audited process or activity, and area (physical or organizational)

Major changes observed? ○ Yes ◉ No

Task 6 Records of supplier evaluation
Auditor: Victor M. Hernandez

I verified through review of the Supplier Assessment procedure MDSAP-1300, Rev. 1, the General Purchasing procedure MDSAP-1200, Rev. 0, and the Receipt, Inspection, Labeling and Inventory Control of OsteoGen Particulates procedure MDSAP-2203, Rev. 3, and qualification records for AMS Micro Medical (TriStar Screws) and Defender (OsteoGen), that the manufacturer does maintain effective controls over suppliers and product, so that specified requirements continue to be met.

I verified the above information by interviewing Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 7.4.1; RDC ANVISA 665/2022: Art. 23; MHLW MO169: 37; 21 CFR 820.50(a).

Task 11 Purchasing control activities as source of quality data for the measurement, analysis, and improvement process
Auditor: Victor M. Hernandez

I verified through review of the the Quality Data Analysis and Management Review Meetings procedure MDSAP-0100, Rev. 2 and Management Review meeting minutes dated 2022-07-01, that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.

I verified the above information by interviewing Andrew Valen, President.
Clause and regulation as applicable: ISO 13485:2016: 8.4; RDC ANVISA 665/2022: Art. 120; MHLW MO169: 61; 21 CFR 820.100

Task 12 Top management commitment to the purchasing process
Auditor: Victor M. Hernandez

I determined, based on the assessment of the overall purchasing, that management provides the necessary commitment to the purchase process.
Clause and regulation: [ISO 13485:2016: 4.1.3, 4.1.5, 5.2; RDC ANVISA 665/2022: Art. 8°, Art. 9°; MHLW MO169: 5-3, 5-5, 11

Selected Supplier File and Rationale for the Selection

AMS Micro Medical (Supplier of the TriStar Screws)
Defender (Supplier of the OsteoGen Plug)

Key documents reviewed related to this specific process or task

Documents Reviewed:
Quality Management System Manual MDSAP-QSM, Rev. 3
Supplier Assessment MDSAP-1300, Rev. 1
General Purchasing MDSAP-1200, Rev. 0
Receipt, Inspection, Labeling and Inventory Control of OsteoGen Particulates MDSAP-2203, Rev. 3
Quality Data Analysis and Management Review Meetings MDSAP-0100, Rev. 2

Records Reviewed:
Qualification Records for: AMS Micro Medical (TriStar Screws)

Qualification Records for: Defender (OsteoGen)
Management Review meeting minutes dated 2022-07-01

Names and Titles of persons interviewed:

Andrew Valen, President
Zachary Adler, Quality Management Rep

Nonconformity? (•) **No** ( ) **Yes**

Concluding statement regarding whether the audited activities/processes are in conformity with the audit criteria

I determined through the review of Purchasing processes that the process did conform to audit criteria. The processes were found to be effective.

Section 12. Nonconformities

Import Nonconformity Information

NC Ref #	Statement of Nonconformity / Supporting Evidence	ISO 13485 Grade

Section 13. Significant Deviations from the Audit Plan

There were no significant deviations from the audit plan.

Duration of the Audit (in auditor-days) Planned 3.5 Actual 3.5

Obstacles

There were no obstacles

Section 14. Follow-up of Past Nonconformities (record details of the review in the nonconformity reports)

☒ Not Applicable

Section 15. Summary of Major Changes to Audited Facility

There have been no major changes to the audited facility

Section 16. CONCLUSIONS

Total # of Open Nonconformities (NC): **0** Including # of NCs from Past Audits Left Open: 0 # of NC Issued During this Audit: 0

	All members of the audit team confirmed their compliance with the SGS Code of Integrity and Professional Conduct and specifically with the SGS Medical Device Impartiality and Conflict of Interest Statement. Audits are based upon sampling and are subject to sampling error. Please be advised that the audit is not intended to provided an exhaustive determination of the compliance of your quality management system. Nonconformities may still exist.
Conformity with Audit Criteria	The audited client is controlling the use of certification documents and marks where applicable. The lead auditor confirms and declares on their own behalf and for all on site audit team members that there is no conflict of interest in performing this audit: Lead Auditor acknowledged: Victor M. Hernandez There were no NC's raised and the audit team confirms the QMS meets all requirements of the audit criteria including ISO 13485:2016 and all applicable regulations.
Effectiveness of the QMS in meeting Quality Objectives	There were no NCs raised so the audit team confirms the QMS meets all requirements of the set quality objectives.
Achievement of Audit Objectives	The audit objectives were met.
Factors encountered that may affect the Audit Reliability	No factors were encounter that affected the reliability of the audit.
Recommendations on the Certification Status	The audit team recommends continued certification since no NCs were raised.
Recommendations on Follow-up Actions	None
Recommendations on **- Audit Program,** **- Audit Team Competence,** **- Audit Duration**	The audit program is the correct duration. The audit duration does match the MDSAP audit duration calculation and also did match IAF MD9 when necessary. The audit team did meet the required codes for the audit. The technical area codes for the audit were correct. The audit duration was acceptable for this audit.

Section 17. Attachments

List of Audit Report Attachments

Audit Plan

List of medical devices

List of critical suppliers

Section 18. Audit Report Approval

Approver **Mary K. Elliott**

Title Quality Assurance Lead, Knowledge

Signature **Mary K Elliott**

Digitally signed by Mary K Elliott
Date: 2023.03.28 08:18:28 -04'00'

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

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

Section 1: General Information

Facility Name: Maclean Health

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

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

City: _____ State: _____ Zip: _____

Telephone: 800-683-4923 Website: www.macleanhealth.com

Name of Designated Representative (DR): Zach Isnec

Licensing Company Email: compliance.macleanhealth@gmail.com DR Email: zisnec@macleanhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☑ Others:	☐ Warehouse
☐ Veterinarians	Over-the-counter (OTC) Drugs, Pseudoephedrine, Gabapentin	☐ Retail pharmacy wholesale distributor
☑ Others: US Federal Government		☑ Others: Virtual Wholesaler

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

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

Name: N/A, no pharmaceutical products sold, dispensed, or distributed within the last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): N/A

Corporation/Organization Name: Maclean Health

Mailing Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Telephone: 800-683-4923 Email: compliance.macleanhealth@gmail.com

Contact Person Name: Zach Isnec

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Date of Event/Arrest	Disposition Date	State	City	County

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

Reason/Charge

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

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/10/23
Date

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

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

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

Maclean Health
Facility Name

Zach Isnec
Print Name of Authorized Person Submitting Application

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

7/10/23
Date

Board Use Only	Date Received: 9/22/23	Amount: 1000-CC

Maclean Health

MacleanRx, a part of Maclean Health, is a Service Disabled Veteran Owned Small Business(SDVOSB) introducing, distributing, and expanding the availability and use of innovative specialty pharmaceuticals throughout the VA, DoD, and in other Federal and State Payers and Purchasers.

Maclean Health is an ISO 9001:2015 certified medical and pharmaceutical products wholesale distributor with a specialization in supplying market innovators.

Our mission is to deliver the highest quality medical and pharmaceutical products to our government clients, leveraging cutting-edge technology and exceptional customer service. With years of experience in the healthcare industry, we have developed a deep understanding of the unique needs and challenges faced by government agencies, and we are dedicated to providing tailored solutions to meet those needs.

We strive to streamline the procurement and contracting process for our clients, identifying opportunities to support and optimize their sales approach and ultimately improving access to their products and services.

Maclean Health

List of Officers

John Deterding
Title/Position: CEO/Owner
Percentage Owned: 100%
[redacted]
Email Address: john@themacleangroup.net

Anthony Joseph Riehl Campos
Title/Position: Chief Financial Officer
[redacted]
Email Address: tcampos@themacleangroup.net

Louis Christopher Tripoli
Title/Position: Chief Medical Officer
[redacted]
Email Address: ltripoli@macleanhealth.com

Secretary of State
Certificate of Status

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

Entity Name:	THE MACLEAN GROUP LLC
Entity No.:	201819110428
Registration Date:	07/08/2018
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

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

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

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

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 02, 2023.

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

Certificate No.: 104801115

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

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8057

ISSUE DATE MARCH 18, 2022

MACLEAN HEALTH
2233 WATT AVE STE 296
SACRAMENTO CA 95825

The above is licensed with the State Board of Pharmacy as a Limited Liability Company.

LIMITED LIABILITY COMPANY
ZACHARY MAKANALANI ISNEC EXEMPTEE IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL MARCH 01, 2024

RECEIPT NUMBER 00184104

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

05/16/23
05/16/23

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 8057

NAME: MACLEAN HEALTH

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

2233 WATT AVE STE 296
SACRAMENTO CA 95825
SACRAMENTO COUNTY

ISSUANCE DATE

MARCH 18, 2022

EXPIRATION DATE

MARCH 1, 2024

CURRENT DATE / TIME

SEPTEMBER 19, 2023
6:22:8 AM

LICENSE RELATIONSHIPS

NAME: ISNEC, ZACHARY MAKANALANI

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)

LICENSE NUMBER: 27103 **PRIMARY STATUS:** CLEAR

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. ACC006002505

Application/License No. _____

The Maclean Group LLC DBA Maclean Health, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
2233 WATT AVENUE SUITE 296 SACRAMENTO, CA 95825, as
Address of Applicant/Principal
PRINCIPAL, and ALLEGHENY CASUALTY COMPANY, a
Surety Company
corporation organized under the laws of the state of NEW JERSEY
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
ONE NEWARK CENTER 20TH FLOOR NEWARK, NJ 07102 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on AUGUST 1, 2023.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

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

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

In witness whereof, each party to this bond has caused it to be executed on this 3RD day of AUGUST, 2023.

APPLICANT/PRINCIPAL
The Maclean Group LLC DBA Maclean Health
COMPANY

Authorized Representative

SURETY Allegheny Casualty Company

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Taylor Branum
Witness

Justin Richmond
Witness

Countersigned by:

Not Needed
Nevada Resident Agent

allegheny
CASUALTY COMPANY

Bond Number: ACC006002505

One Newark Center, 20th. Floor, Newark, New Jersey, 07102-5207
PHONE: (973) 624-7200

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That **ALLEGHENY CASUALTY COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, having its principal office in the City of Newark, New Jersey, does hereby constitute and appoint

Eric Fauerbach

its true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **ALLEGHENY CASUALTY COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **ALLEGHENY CASUALTY COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **ALLEGHENY CASUALTY COMPANY** at a meeting duly held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-Fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **ALLEGHENY CASUALTY COMPANY** has executed and attested these presents on this 31st day of December 2021

ALLEGHENY CASUALTY COMPANY CORPORATE SEAL 1936 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

Robert Kersnick
Vice President, ALLEGHENY CASUALTY COMPANY

On this 31st day of December, 2021, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of ALLEGHENY CASUALTY COMPANY; that the seal affixed to said instrument is the Corporate Seal of said Company; that the said Corporate Seal and his signature were duly affixed by order of the Boards of Directors of said Company.

Michele A Aleman NOTARY PUBLIC MY COMMISSION EXPIRES 10-18-2024 NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written

Michele A Aleman, a Notary Public of New Jersey
My Commission Expires October 18, 2024

CERTIFICATION

I, the undersigned officer of **ALLEGHENY CASUALTY COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Company as set forth in said Power of Attorney, with the originals on file in the home office of said company, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this 3rd day of August 2023

James Portman, Secretary

August 3, 2023

SURETY BONDS DIRECT
4900 O'Hear Ave Ste 206
North Charleston, SC 29405

1-800-608-9950
service@suretybondsdirect.com
www.suretybondsdirect.com

Order: W3A4E24257

JOHN DETERDING
THE MACLEAN GROUP LLC
2233 WATT AVENUE
SUITE 296
SACRAMENTO, CA 95825

Your official bond is enclosed.
Thank you for your purchase!

Congratulations!
Your official surety bond documents from Surety Bonds Direct are enclosed.

Bond: Pharmaceutical Wholesaler Bond
Bonded: The Maclean Group LLC

What To Do Now

1. Please review the documents carefully and make sure to fill in any blanks and sign as required.
2. Carefully follow all submission and other instructions provided to you by the obligee (state, local, federal government or private party requiring you to purchase the bond). If you have any questions about this process, it is best to contact the obligee directly for assistance since requirements vary.

If you need to make changes to your bond or have any questions for us, we are here to help.
Just call us at **1-800-608-9950** or send us an email at **service@suretybondsdirect.com**.

Stay In Touch

- Visit our site: **www.suretybondsdirect.com**
- Follow us on Twitter **@DirectBonds**
- Like us on Facebook **@SuretyBondsDirect**

We'll provide you with the latest developments in surety bonding that affect you, including expert insights, guidance on industry trends & requirements, and more.

We appreciate your business!

Sincerely,
All of us at Surety Bonds Direct

THEMACL-01 LMANZER

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/19/2023

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

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

PRODUCER	CONTACT NAME: Tracy Dolan
Alliant Insurance Services, Inc. 2355 Gold Meadow Way Ste 143 Gold River, CA 95670	PHONE (A/C, No, Ext): (916) 210-0317 FAX (A/C, No): (916) 210-0343 E-MAIL ADDRESS: tracy.dolan@alliant.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE Fire Underwriters Insurance Company	20702C
INSURER B : Great Northern Insurance Company	20303
INSURER C : ACE Property & Casualty Insurance Company	20699
INSURER D : Chubb National Insurance Company	10052
INSURER E :	
INSURER F :	

INSURED

The Maclean Group, LLC
2233 Watt Ave Suite 296
Sacramento, CA 95825

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR			D96705773	11/15/2023	11/15/2024	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	Included
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	Excluded
	OTHER:							$	
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	ANY AUTO			73630606	11/15/2023	11/15/2024	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY X SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
C	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE			D98369715	11/15/2023	11/15/2024	AGGREGATE	$	5,000,000
	DED X RETENTION $ 0							$	
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N/A			71800822	11/15/2023	11/15/2024	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000

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

CERTIFICATE HOLDER

Evidence of Coverage

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: The Maclean Group, LLC — MDEG License # (if applicable): N/A

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento — State: CA — Zip: 95825

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

City: — State: — Zip:

Telephone: 800-683-4923 — Website: www.macleanhealth.com

Licensing Company Email: compliance.macleanhealth@gmail.com

Section 2: Personal Information

First: Zachary — Middle: Makanalani — Last: Isnec

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

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

Mailing Address: [redacted]

City: Sacramento — State: CA — Zip: 95815

Telephone: [redacted] — Email: zisnec@macleanhealth.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Home-schooled		08/1999 - 04/2003	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2021 - Current	[redacted]	Sacramento	CA	95815
05/2020 - 05/2021		Sacramento	CA	95608
09/2014 - 05/2020		Sonora	CA	95370
08/2011 - 09/2014		Sonora	CA	95370
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
Maclean Health			02/2023 - current
Business Address	**City**	**State**	**Zip**
2233 Watt Avenue, Suite 296	Sacramento	CA	95825
Phone	**Title**	**Number of Employed Hours**	
916-270-2104	Pharmaceutical Administrative Manager	1240	

Description of Duties
Ensures full compliance with state laws and regulations related to pharmaceutical distribution. Oversees the verification of pharmaceutical products to ensure they meet all quality and safety standards before distribution. Maintains accurate and organized records of all pharmaceutical transactions, including sales, returns, and inventory. Acts as a liaison between our company and regulatory authorities, responding promptly to inquiries and facilitating inspections as needed. Provides training and guidance to employees involved in pharmaceutical distribution to ensure adherence to regulatory requirements. Conducts internal audits to identify and rectify any compliance issues, and assist with external audits as required. Generates and submits required reports to regulatory authorities in a timely manner.

Business Name			From - To (MM/YY – MM/YY)
Optum Infusion Pharmacy			05/2020 - 03/2021
Business Address	**City**	**State**	**Zip**
4610 Northgate Boulevard Suite 130	Sacramento	CA	95834
Phone	**Title**	**Number of Employed Hours**	
877-698-5415	Patient Service Representative / Senior Pharmacy Technician	1880	

Description of Duties
Contacted patients and their caregivers to arrange monthly IG deliveries Verified and updated patient demographics Gathered pertinent patient for prior authorization requests Audited supply usage to assure only necessary items are shipped Accurately dispensed IG, ancillary infusions, and premed treatments Pulled supplies and assembled all items for shipment Responded to patient inquiries regarding deliveries and insurance Submitted claims to PBMs, attached prior authorizations to claims, and troubleshot as needed Cycle counted drugs and supplies on a monthly basis to assure accurate inventory is reflected in database

Business Name			From - To (MM/YY – MM/YY)
Adventist Health Sonora			03/2011 - 05/2020
Business Address	**City**	**State**	**Zip**
1000 Greenley Road	Sonora	CA	95370
Phone	**Title**	**Number of Employed Hours**	
(209) 536-3820	Senior Pharmacy Technician	19280	

Description of Duties
Reduced supply shortages by carefully monitoring inventory and submitting replenishment orders before depletion Performed various pharmacy operational activities with strong commitment to accuracy, efficiency and service quality Maintained and repaired facilities, equipment and tools to ensure operational readiness, safety and cleanliness Ensured compliance with policies and quality standards to maintain consistency in quality of services Prepared intravenous solutions, admixtures and other solutions using aseptic techniques Restocked automated medication dispensing equipment Repaired and troubleshot medication dispensing equipment Trained all new pharmacy staff in policies and procedures to ensure smooth operations

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

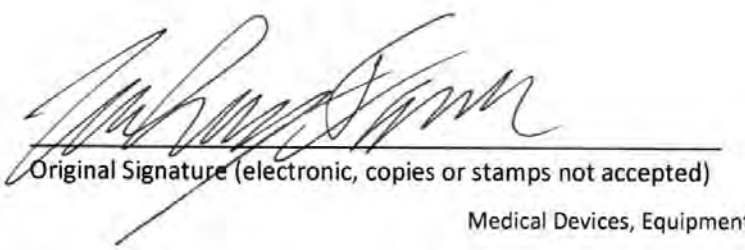
Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted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

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

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

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

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

10/07/2023

Date

I, Zachary Makanalani Isnec, **certify that as the MDEG Administrator for**

The Maclean Group, LLC,

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

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

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zachary Isnec
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/03/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Maclean Health

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 800-683-4923 Website: www.macleanhealth.com

Licensing Company Email: compliance.macleanhealth@gmail.com

Section 2: Personal Information

First: Zachary Middle: Makanalani Last: Isnec

Alias(es, nicknames, name changes, etc.): Zach

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Telephone: 800-683-4923 Email: compliance.macleanhealth@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Homeschooled		08/99-04/03	
Address	**City**	**State**	**Zip**
N/A	N/A	N/A	N/A
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/21 - Current	[redacted]	Sacramento	CA	95815
From - To (MM/YY – MM/YY) 05/20 - 05/21		Carmichael	CA	95608
From - To (MM/YY – MM/YY) 09/14 - 05/20		Sonora	CA	95370
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Maclean Health			02/23 - Current
Business Address	**City**	**State**	**Zip**
2233 Watt Avenue, Suite 296	Sacramento	CA	95825
Phone	**Title**		**Number of Employed Hours**
916-270-2104	Pharmaceutical Administrative Manager		720

Description of Duties
Serves as the designated representative-in-charge for all pharmaceutical licenses
Authored pharmaceutical division SOPs
Manager of ISO 9001:2015 compliance
Kept scrupulous records of acquisition, destruction, and disposition for all dangerous drugs and devices
Manager of pharmaceutical compliance

Business Name			From - To (MM/YY – MM/YY)
Optum Infusion Pharmacy			05/20 - 03/21
Business Address	**City**	**State**	**Zip**
4610 Northgate Boulevard Suite 130	Sacramento	CA	95834
Phone	**Title**		**Number of Employed Hours**
8776985415	Patient Service Representative / Senior Pharmacy Technician		1880

Description of Duties
Contacted patients and their caregivers to arrange monthly IG deliveries
Verified and updated patient demographics
Gathered pertinent patient for prior authorization requests
Audited supply usage to assure only necessary items are shipped
Accurately dispensed IG, ancillary infusions, and premed treatments
Pulled supplies and assembled all items for shipment
Responded to patient inquiries regarding deliveries and insurance
Submitted claims to PBMs, attached prior authorizations to claims, and troubleshot as needed
Cycle counted drugs and supplies on a monthly basis to assure accurate inventory is reflected in database

Business Name			From - To (MM/YY – MM/YY)
Adventist Health Sonora			03/11 - 05/20
Business Address	**City**	**State**	**Zip**
1000 Greenley Road	Sonora	CA	95370
Phone	**Title**		**Number of Employed Hours**
2095365000	Senior Pharmacy Technician		19280

Description of Duties
Monitored ordering of pharmacy medication stock to maintain streamlined inventory and low overhead
Reduced supply shortages by carefully monitoring inventory and submitting replenishment orders before depletion
Performed various pharmacy operational activities with strong commitment to accuracy, efficiency and service quality
Maintained and repaired facilities, equipment and tools to ensure operational readiness, safety and cleanliness
Ensured compliance with policies and quality standards to maintain consistency in quality of services
Prepared intravenous solutions, admixtures and other solutions using aseptic techniques
Restocked automated medication dispensing equipment
Repaired and troubleshot medication dispensing equipment
Trained all new pharmacy staff in policies and procedures to ensure smooth operations

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/10/23
Date

I, Zachary Isnec, **certify that as the designated representative for**

Maclean Health,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZI I am at least 21 years of age;
3. ZI I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZI I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZI I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZI I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZI I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Zach Insec
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/10/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zachary Isnec
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/10/23
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, Zachary Isnec, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/12/23
Date

Subscribed and Sworn to before me this 12th day of July 2023.

Notary Public Signature

CA Notary Attached

(Seal)

Nevada State Board of Pharmacy
Wholesaler Application

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sacramento

Subscribed and sworn to (or affirmed) before me on this 12th day of July, 2023, by Zachary Isaac,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

MEGAN ANN LEA
COMM. # 2335016
NOTARY PUBLIC - CALIFORNIA
SACRAMENTO COUNTY
COMM. EXPIRES OCT. 8, 2024

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Maclean Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 800-683-4923 Website: www.macleanhealth.com

Licensing Company Email: compliance.macleanhealth@gmail.com

Section 2: Personal Information

First: John Middle: Ryan Last: Deterding

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Sacramento State: CA Zip: 95825

Telephone: [redacted] Email: compliance.macleanhealth@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California			
Address	**City**	**State**	**Zip**
University Avenue and, Oxford St	Berkeley	CA	94720
Diploma/Degree obtained, if any			
J.D.			

School Name		From - To (MM/YY – MM/YY)	
United States Naval Academy			
Address	**City**	**State**	**Zip**
121 Blake Road	Annapolis	MD	21402
Diploma/Degree obtained, if any			
B.S. Political Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20- Present	[redacted]	Sacramento	CA	95825
02/19 - 03/20		Albany	CA	94706
05/17 - 02/19		Albany	CA	94706
05/15- 05/17		Sacramento	CA	95814
05/14 - 05/15		Denver	CO	80202
07/13 - 05/14		Denver	CO	80202
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
The Maclean Group			07/18 - Present	
Business Address		**City**	**State**	**Zip**
2233 Watt Avenue, Suite 296		Sacramento	CA	95825
Phone	**Title**			
916-284-0273	Owner/President			

Description of Duties

Founder and CEO of healthcare products distribution company specializing in providing innovative healthcare solutions to the Department of Veteran Affairs, Department of Defense, and other government agencies. Led the company's launch of multiple divisions, including consumables, medical devices, specialty pharmaceuticals, and medical facility engineering equipment. Responsible for day-to-day management of partnerships with multiple Fortune 500 companies and government agencies, as well as company's overall business plan and strategic direction. Achieved revenues in excess of $175M in 2022.

Business Name			From - To (MM/YY – MM/YY)	
Justice at Last			08/18 - 09/21	
Business Address		**City**	**State**	**Zip**
PO Box 566		San Carlos	CA	94070
Phone	**Title**			
650-918-0719	Board of Directors, Member			

Description of Duties

Work with fellow board members, founding attorney, and staff of the only nonprofit law firm in Northern California exclusively serving victims of human trafficking crimes. In addition to general board activities, I participate in industry legal trainings, work on projects that include legal research and memo drafting, and join in community outreach events.

Business Name			From - To (MM/YY – MM/YY)	
Sacramento County District Attourney			08/15 - 09/16	
Business Address		**City**	**State**	**Zip**
901 G Street		Sacramento	CA	95814
Phone	**Title**			
916-874-6218	Intern			

Description of Duties

Provided support to the Sacramento County District Attorney's office through all means of administrative and legal aid work. Worked directly with the DAs at every stage of the prosecutorial process, including: researching, writing and filing motions and oppositions, preparing expert testimony, evaluating evidence, and assisting in trial preparation. Developedformal presentations for use in multiple felony trials, to include several high-profile, violent criminal trials.

Business Name			From - To (MM/YY – MM/YY)	
Nalco an Ecolab Company			06/13 - 06/15	
Business Address		**City**	**State**	**Zip**
1601 West Diehl Road		Naperville	IL	60563
Phone	**Title**			
800-288-0878	Account Engineer / Manager			

Description of Duties

Managed the technical consulting and sales processes of complex chemical applications for over 35 clients across the Midwest, constituting a portfolio of over $1.2M. Ranked #1 in district of 14 personnel, and 4th overall out of nearly 800 employees in North America. Accomplished a territory growth rate of over 100% during 2014 sales year.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

July 11, 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Deterding
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 11, 2023
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, John Deterding, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/12/23
Date

Subscribed and Sworn to before me this 12th day of July 2023.

Notary Public Signature

CA Notary Attached

(Seal)

Nevada State Board of Pharmacy
Personal History Application

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sacramento

Subscribed and sworn to (or affirmed) before me on this 12th day of July, 2023, by John Deterding,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

MEGAN ANN LEA
COMM. # 2335016
NOTARY PUBLIC - CALIFORNIA
SACRAMENTO COUNTY
COMM. EXPIRES OCT. 8, 2024

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Maclean Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 800-683-4923 Website: www.macleanhealth.com

Licensing Company Email: compliance.macleanhealth@gmail.com

Section 2: Personal Information

First: Anthony Middle: Joseph Riehl Last: Campos

Alias(es, nicknames, name changes, etc.): Tony

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Carmichael State: CA Zip: 95608

Telephone: [redacted] Email: compliance.macleanhealth@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
THE WHARTON SCHOOL, UNIVERSITY OF PENNSYLVANIA		08/14 – 05/16	
Address: 3733 Spruce Street	City: Philadelphia	State: PA	Zip: 19104.6340
Diploma/Degree obtained, if any: Master of Business Administration; Major in Entrepreneurial Management & Strategic Management			

School Name		From - To (MM/YY – MM/YY)	
MCDONOUGH SCHOOL OF BUSINESS, GEORGETOWN UNIVERSITY		08/03 - 05/07	
Address: 37th and O Streets, N.W.	City: Washington	State: D.C.	Zip: 20057
Diploma/Degree obtained, if any: Bachelor of Science, Business Admin.; Major in Finance & International Business; Minor in Spanish			

School Name		From - To (MM/YY – MM/YY)	
Jesuit High School		08/99 – 05/03	
Address: 1200 Jacob Lane	City: Carmichael	State: CA	Zip: 95608
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any:			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/17 - Present	[redacted]	Carmichael	CA	95608
02/21 - Present		Los Angeles	CA	90049
10/16 - 09/17		Seattle	WA	98102
08/14 - 05/16		Philadelphia	PA	19103
02/11 - 08/14		New York	NY	10013
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MACLEAN HEALTH			2019-Present
Business Address	**City**	**State**	**Zip**
2233 Watt Avenue, Suite 296	Sacramento	CA	95825
Phone	**Title**		
800-683-4923	Chief Financial Officer and Member of the Board of Directors		

Description of Duties

- Oversee the financial operations of the The Maclean Group (dba Maclean Health and MacleanRx).
- Co-lead partnerships with manufacturers to grow revenue for the Company.
- Help expand the Company's offering to include various government and commercial procurement opportunities.

Business Name			From - To (MM/YY – MM/YY)
SAMESKY HEALTH (formerly ConsejoSano)			2019-2020
Business Address	**City**	**State**	**Zip**
5250 Lankershim Blvd. Suite 520	North Hollywood	CA	91601
Phone	**Title**		
(707) 382-9233	Vice President of Operations, 2020 / Senior Director of Operations, 2020 / Director of Operations, 2019		

Description of Duties

- As second business hire, led various projects across business operations: market mapping of social determinants of health (SDOH) tech startups for potential partnership expansion, analyzed ROI for payer & provider clients, captured more data across clients to increase sales opportunities, led internal fundraising process for Series B capital raise ($17M), coanalyzed two potential merger opportunities, and provided strategic analysis for ad-hoc projects for Board of Directors.
- Built data analytics team to prove efficacy of Company's engagement efforts to investors, current & potential clients; managed 7 direct reports across the data and operations teams.
- Spent 25% of the time in a business development role, bringing in 6 additional clients, including Anthem, Inc.

Business Name			From - To (MM/YY – MM/YY)
MEDRA HEALTH, INC. (previously Pivot Health)			2016-2018
Business Address	**City**	**State**	**Zip**
720 14th Street	Sacramento	CA	95814
Phone	**Title**		
	Founder, CEO (oversaw Operations, Partnerships, and Finance)		

Description of Duties

- Built online marketplace and digital workforce management software that improved talent sourcing for healthcare providers while utilizing proprietary data to drive recommendations to healthcare organizations.
- Led all partnerships, enterprise sales, and business operations of the company.
- Awards Received: Selected into Wharton Venture Initiation Program Accelerator; iLab Accelerator at Kapor Center; Tech Futures Group; Winner, Penn-Wharton Innovation Fund Grant; Semifinalist—Stanford Cardinal Ventures Pitch Competition and Stanford Entrepreneurship Society V3 (2018); Top 5% Applicant at StartX (Stanford's incubator).

Business Name			From - To (MM/YY – MM/YY)
D.F. KING & CO., INC. (Pacific Equity Partners portfolio company)			~~2013-2014~~ 2009-2014
Business Address	**City**	**State**	**Zip**
48 Wall St	New York	NY	10005
Phone	**Title**		
(212) 269-5550	Asst. Vice President		

Description of Duties

- Helped design a strategy with advisor team to defend eBay Inc. against Icahn's hostile attempt to force the board of directors of eBay to spin-off its PayPal unit and elect members of Icahn's team to eBay's board.
- Developed strategy with Icahn Capital to attempt to block the Dell Inc. take private transaction.
- Analyzed and spearheaded the expansion of the firm's services into Latin America, which contributed to 10 additional clients. Designed business plan and implementation strategy, which later gained approval of CEO.
- Managed cross-functional team of 9 direct reports to conduct primary and secondary research.
- Youngest in firm's history to be promoted from Analyst to Assistant Vice President.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anthony Campos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/14/23

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Anthony Campos, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/14/23

Date

Subscribed and sworn to before me this _____ day of _____.

See Attached

Notary Public Signature

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 14 day of JULY, 20 23, by ANTHONY JOSEPH RIEHL CAMPOS, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

YELENA OSADCHAYA
Notary Public - California
Los Angeles County
Commission # 2331092
My Comm. Expires Aug 26, 2024

(Seal)

Signature

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Maclean Health

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 2233 Watt Avenue, Suite 296

City: Sacramento State: CA Zip: 95825

Mailing Address (if different from physical address): same as physical address

City: State: Zip:

Telephone: 800-683-4923 Website: www.macleanhealth.com

Licensing Company Email: compliance.macleanhealth@gmail.com

Section 2: Personal Information

First: Louis Middle: Christopher Last: Tripoli

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: 89183

Telephone: [redacted] Email: compliance.macleanhealth@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh School of Medicine		09/80-05/84	
Address	**City**	**State**	**Zip**
3550 Terrace St	Pittsburgh	PA	15213
Diploma/Degree obtained, if any			
Doctor of Medicine (M.D.)			

School Name		From - To (MM/YY – MM/YY)	
Harvard University		09/76-06/80	
Address	**City**	**State**	**Zip**
Massachusetts Hall	Cambridge	MA	02138
Diploma/Degree obtained, if any			
Bachelor of Arts (B.A.)			

School Name		From - To (MM/YY – MM/YY)	
The Kiski School		09/72-06/76	
Address	**City**	**State**	**Zip**
1888 Brett Lane	Saltsburg	PA	15681
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21-current	[redacted]	Las Vegas	NV	89183
11/20-04/21		Las Vegas	NV	89118
02/18-11/20		Kaneohe	HI	96744
03/17-02/18		Reno	NV	89511
07/08-03/17		Ramona	CA	92065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Maclean Health			
Business Address	**City**	**State**	**Zip**
2233 Watt Avenue, Suite 296	Sacramento	CA	95825
Phone	**Title**		
800-683-4923	Chief Medical Officer		
Description of Duties			
Advise on medical and healthcare-related products and services.			

Business Name			From - To (MM/YY – MM/YY)
MedImpact Healthcare Systems, Inc			07/08-12/16
Business Address	**City**	**State**	**Zip**
10181 Scripps Gateway Court	San Diego	CA	92131
Phone	**Title**		
800 788-2949	Medical Director		
Description of Duties			
Pharmacy Formulary review. Head of Pharmacy and Therapeutics Committee.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
7/9/1992	11/8/1994	PA	Washington	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
C-63-CV-199203601	Court of Common Pleas, Washington County, PA

Reason/Charge
Medical liability

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Plaitiff: Catherine Wilson	Civil lawsuit

Name of Business/Industry/Entity
Louis Tripoli, MD (physician)

Provide explanation below:

Records attached. Patient filed a lawsuit in July 1992 against me and other doctors over her care; her legal team was unable to identify a medical expert that could provide them sufficient reason to go forward with the case, and it was withdrawn by them in November 1994 and closed. There was no judgment, and no damages.

Louis Tripoli MD

Original Signature (electronic, copies or stamps not accepted)

8/4/2023

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2000	3/15/2001	IL	Chicago	Cook
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
99C3155		United States District Court, N.D. Illinois, Eastern Division		
Reason/Charge				
Defamation				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Plaintiff: Andrew Skolnick			Civil case	
Name of Business/Industry/Entity				
Correctional Medical Services Inc				

Provide explanation below:

Records attached. When I was the Chief Medical Officer of Correctional Medical Services, a company that provided health services for prison inmates, the plaintiff Mr. Skolnick sued my boss Richard Miles and me and the company for defamation because I wrote a letter to his employer complaining about a story he wrote for a newspaper. The case was dismissed on a motion for summary judgment.

Original Signature (electronic, copies or stamps not accepted)

8/4/2023
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1997	2007	MO	Saint Louis	Saint Louis County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
various	various jurisdictions

Reason/Charge
lawsuits brought by prison inmates

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
several	various

Name of Business/Industry/Entity
Correctional Medical Services, Inc.

Provide explanation below:

From November 1997 until December 2007, I was the Chief Medical Officer of a company, Correctional Medical Services, Inc., based in St. Louis, Missouri, except for two periods of time when I was on active military duty - May 2004 to May 2005, and August 2006 until December 2007. The company provided health services to inmates in prisons and jails in hundreds of locations throughout the United States. Unfortunately, prisoners are likely to file lawsuits for many reasons. In the case of health care, the most common lawsuits are those that allege violation of constitutional and civil rights, as opposed to medical liability, but there are various combinations of complaint types. I do not know how many lawsuits were brought during my tenure at the company, probably dozens. I have no records, and the company went out of existence years ago. I do not recall any situation in which any of the cases resulted in a successful judgment against the company, but there may have been some. Certainly there was never an occasion that affected me personally from the perspective of financial or other penalties. It would be difficult to identify or find all the records related to this company during this time.

Louis Truscello

Original Signature (electronic, copies or stamps not accepted)

8/4/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Louis Tripoli

Print Name (First, Last)

Louis Tripoli

Original Signature (electronic, copies or stamps not accepted)

8/8/2023 LCT ~~8/4/2023~~

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Louis Tripoli, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Louis Tripoli

Original Signature

8/8/2023

Date

Subscribed and Sworn to before me this 8 day of Aug. 2023

Michele Williams

Notary Public Signature

MICHELE WILLIAMS
Notary Public, State of Nevada
No. 05-99624-1
My Appt. Exp. Aug. 29, 2025

(Seal)

IN THE COURT OF COMMON PLEAS OF WASHINGTON COUNTY, PENNSYLVANIA

CATHERINE I. WILSON,

Plaintiff,

v.

JOHN E. FRAZIER II, M.D., NEIL J. HART, M.D., JAMES T. HOPKINS, M.D. and LOUIS C. TRIPOLI, M.D.,

Defendants.

No. 92-3601

FILED
94 NOV -9 PM 1:16
PROTHONOTARY
WASHINGTON CO. PA.

To the Prothonotary:

Kindly discontinue the civil action at the above-captioned number.

CERTIFICATE OF SERVICE

I CERTIFY THAT A TRUE AND CORRECT COPY OF THE FOREGOING WAS MAILED POSTAGE PAID TO ADVERSE COUNSEL, THIS 8th DAY OF Nov., 19 94

ATTORNEY FOR Plaintiff

Respectfully submitted,

Bruce S. Gelman, Esquire
Attorney for Plaintiff

Gelman & Reisman
1701 Law & Finance Building
Pittsburgh, PA 15219

(412) 288-9200

Court of Common Pleas
Washington County
Commonwealth of Pennsylvania

Full Docket Print for Case #: **C-63-CV-199203601** **Judge:**

Case Title: WILSON vs. FRAZIER
Case Type: SUMMONS-CIVIL ACTION
Status: CLOSED

Trial List Number:

Party Details

PLAINTIFF # 1 WILSON CATHERINE I

Party Status: ACTIVE as of 2/10/2001

OF
WASHINGTON, PA 15301

DEFENDANT # 1 FRAZIER JOHN E II

Party Status: ACTIVE as of 2/10/2001

[redacted]
PITTSBURGH, PA 15212

DEFENDANT # 2 HART NEIL J

Party Status: ACTIVE as of 2/10/2001

[redacted]
PITTSBURGH, PA 15212

DEFENDANT # 3 HOPKINS JAMES T

Party Status: ACTIVE as of 2/10/2001

[redacted]
NEWARK, DE 19713

DEFENDANT # 4 TRIPOLI LOUIS C

Party Status: ACTIVE as of 2/10/2001

[redacted]
WASHINGTON, PA 15301

Event Summary

Court of Common Pleas
Washington County
Commonwealth of Pennsylvania

Full Docket Print for Case #: **C-63-CV-199203601** **Judge:**

06/11/1992	4581	1	SUMMONS-CIVIL ACTION	
07/28/1992	4034	1	APPEARANCE OF	WM.D.PHILLIPS,ESQ & MARK NEFF,ESQ FOR DFTS,J.E.FRAZIER,II,M.D.,N.J. HART,M.D. & J.T.HOPKINS,M.D. & RULE ISSUED ON PLF TO FILE COM-PLAINT
08/06/1992	4001	1	ACCEPTANCE OF SERVICE BY	BRUCE GELMAN,ESQUIRE OF RULE ON BEHALF OF PLTF 8-4-92
09/04/1992	4184	1	SERVED	DEFTS J.E.FRAZIER,II M.D.& N.J. HART M.D.7-8-92 NOT FOUND AS TO DEFT,J.T.HOPKINS M.D.UNKNOWN, SERVED DEFT,L.C.TRIPOLI,M.D. 7-9-92
09/10/1992	4034	1	APPEARANCE OF	G,G & D,BY DANIEL P.CARROLL,ESQ FOR DFT,LOUIS C.TRIPOLI
09/10/1992	4182	2	RULE TO FILE COMPLAINT UPON	PLTF,BY DFT,LOUIS C.TRIPOLI
09/21/1992	4049	1	COMPLAINT	IN CIVIL ACTION BY PLTF
09/22/1992	4001	1	ACCEPTANCE OF SERVICE BY	DEFT,BRUCE S GELMAN,ESQ OF RULE TO FILE COMPLAINT 9-17-92
09/24/1992	4226	1	CERTIFICATION	OF SERVICE OF COMPLAINT IN CIVIL ACTION UPON COUNSEL FOR DEFTS J.E.FRAZIER,II,N.J.HART & J.T. HOPKINS 9-23-92,L.C.TRIPOLI 9-22-92
10/21/1992	4023	1	ANSWER	TO COMPLAINT IN CIVIL ACTION & NEW MATTER BY DEFT,LOUIS C TRIPOLI,M.D
10/29/1992	4166	1	PRELIMINARY OBJECTIONS OF	DFTS,J.E.FRAZIER II,MD,N.J.HART,MD & J.T.HOPKINS,MD.T/PLFS COMP & ORDER:ORAL ARGMT:2-25-93 @ 1:30 PM BEF T/UNDERSIGNED.BRIEFS IN OPP BY 1-8-93.TERPUTAC J
10/29/1992	4282	2	MEMORANDUM	IN SUPPORT OF PREL OBJS TO PLTFS COMPLAINT BY DEFTS
11/04/1992	4208	1	ORDER	SCHEDULING ARGUMENT FOR 10-29-92 VACATED.PREL OBJS S/BE DETERMINED ON BRIEFS.OPPOSING BRIEFS,IF ANY, T/PREL OBJS S/BE FILED BY 12-11-92 TERPUTAC J,COPIES SENT 11-2-92,SP
12/07/1992	4176	1	REPLY TO NEW MATTER	OF DEFT,LOUIS C TRIPOLI,M.D.BY PLTF
12/10/1992	4289	1	BRIEF	IN OPPOSITION TO PRELIM OBJS OF DFTS,JOHN E.FRAZIER,II,M.D.,NEIL J.HART,M.D. & JAMES T.HOPKINS,M.D. BY PLTF
03/01/1993	4229	1	NOTICE	OF SERVICE OF INTERROGATORIES UPON PLTF'S ATTY,BRUCE S GELMAN, ESQ.2-26-93
03/05/1993	4208	1	ORDER	PLTF GRANTED LEAVE TO FILE AN AMENDED COMPLAINT W/IN 20 DAYS OF THE DATE OF THIS ORDER (SEE PAPER) TERPUTAC J,COPIES SENT 3-8-93
03/25/1993	4018	1	AMENDED COMPLAINT	AS TO DFTS,JOHN E.FRAZIER II,M.D., NEIL J.HART,M.D. & JAMES T. HOPKINS,M.D.,BY PLTF
04/06/1993	4260	1	RECEIVED	SUBSTITUTION OR VERIFICATION BY PLTF,CATHERINE I WILSON 3-29-93
04/19/1993	4188	1	STIPULATION	BY PLTF

Court of Common Pleas
Washington County
Commonwealth of Pennsylvania

Full Docket Print for Case #: **C-63-CV-199203601** **Judge:**

04/28/1993	4023	1	ANSWER	BY DEFT TRIPOLI TO AMENDED COMP AS TO DEFTS J.E.FRAZIER,II MD.,N.J. HART,MD.,& J.T.HOPKINS,MD & NEW MATTER
06/07/1993	4176	1	REPLY TO NEW MATTER	OF DFT,LOUIS C.TRIPOLI,M.D.,BY PLTF
06/24/1993	4021	1	ANSWER AND NEW MATTER BY	DEFTS J.E.FRAZIER,II,N.J.HART & J.T.HOPKINS,TO PLTFS COMPLAINT
06/28/1993	4074	1	MOTION	& ORDER PLTF SHALL RESPOND TO THE INTERROGATORIES FORWARDED TO PLTFS COUNSEL ON OR ABOUT 11-16-92 WITHIN 20 DAYS.TERPUTAC J
07/13/1993	4176	1	REPLY TO NEW MATTER	OF DEFTS JOHN E FRAZIER,II,M.D.; NEIL J.HART,M.D.;JAMES T HOPKINS, M.D. & LOUIS C TRIPOLI,M.D.BY PLTF
02/07/1994	4208	1	ORDER	& NOTICE TO:BRUCE S.GELMAN,ESQ TO FILE PRE-TRIAL STATEMENT W/IN 20 DAYS OF MAILING OF THIS ORDER TERPUTAC,J COPIES 2-8-94
03/01/1994	4074	1	MOTION	F/EXTENSION OF TIME TO COMPLETE DISCOVERY & FILE PRE-TRIAL STMTS JOINT! & ORDER:MTN GRNTD;DISCOVE-RY EXTENDED 90 DAYS FROM THE DATE OF THIS ORDER.TERPUTAC J
07/07/1994	4082	1	MOTION FOR SUMMARY JUDGMENT	BY DFTS,J.E.FRAZIER,II,N.J.HART & J.T.HOPKINS & ORDR FOR ARGUMENT ON 11-3-94,1:30 PM BEFORE UNDRSGND OPPOSING BRFS TO BE FILED BY 9-15-94; TERPUTAC,J
07/07/1994	4289	2	BRIEF	IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT,BY FRAZIER,HART & HOPKINS
09/01/1994	4289	1	BRIEF	IN SUPPORT OF MOTION FOR SUM JUDG BY DEFT,LOUID C TRIPOLI
09/01/1994	4082	2	MOTION FOR SUMMARY JUDGMENT	& ORDER ARGUMENT ON DEFT TRIPOLI'S MTN F/SUM JUDG 11-3-94 @ 1:30 P.M. AT 1:30 P.M.REPLY BRIEFS BY 10-14-94.TERPUTAC J,SEE PAPER
11/09/1994	4101	1	PRAECIPE TO DISCONTINUE	BY BRUCE S GELMAN ATTY FOR PLTF
03/07/1995	4256	1	REMOVED FROM ACTIVE FILES	

Judgement Summary

Judgment seq:
Judgement Date:
Judgement Text:
Judgement Amt:
Judgement Code:

Party Details	(C)orp or (P)erson
	C

IN THE COURT OF COMMON PLEAS OF WASHINGTON COUNTY, PENNSYLVANIA

CATHERINE I. WILSON,

Plaintiff,

v.

JOHN E. FRAZIER II, M.D., NEIL J. HART, M.D., JAMES T. HOPKINS, M.D. and LOUIS C. TRIPOLI, M.D.,

Defendants.

CIVIL DIVISION

No. 92-3601

Issue No.

Code: 007

COMPLAINT IN CIVIL ACTION

Filed on Behalf of CATHERINE I. WILSON, Plaintiff

Counsel of Record for this Party:

BRUCE S. GELMAN, ESQUIRE
PA I.D. #41112

JANET S. LIVENGOOD, ESQUIRE
PA I.D. #64376

1701 Law & Finance Building
Pittsburgh, PA 15219

(412)288-9200

JURY TRIAL DEMANDED

FILED
SEP 21 ... 3:53

NOTICE TO DEFEND

You have been sued in Court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written Appearance personally or by attorney and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the Complaint or for any other claim or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

Lawyer Referral Service
The Allegheny County Bar Association
400 Koppers Building
Pittsburgh, Pennsylvania 15222
(412)261-2088

DEMAND FOR JURY TRIAL

In accordance with Pennsylvania Rule of Civil Procedure No. 1007.1, a JURY TRIAL is hereby demanded.

NOTICE TO DEFEND

You have been sued in Court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written Appearance personally or by attorney and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so, the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in this Complaint or for any other claim or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

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Lawyer Referral Service
523 Washington Trust Building
Washington, PA 15301
(412)225-6710

IF YOU CANNOT AFFORD A LAWYER, CONTACT:

Southwestern Pennsylvania Legal Aid Society
10 West Cherry Avenue
Washington, PA 15301
(412)225-6170

DEMAND FOR JURY TRIAL

In accordance with Pennsylvania Rule of Civil Procedure No. 1007.1, a JURY TRIAL is hereby demanded.

COMPLAINT IN CIVIL ACTION

1. At all times material, Plaintiff, CATHERINE I. WILSON, was and is an adult individual residing within the City of Washington, Washington County, and in the Commonwealth of Pennsylvania.

2. At all times material, Defendant, JOHN E. FRAZIER II, M.D., (hereinafter referred to as "FRAZIER") was and is an adult individual licensed to practice medicine within the Commonwealth of Pennsylvania with his principal office located at 420 East North Avenue, Suite 202, Pittsburgh, Allegheny County, Pennsylvania 15212. Plaintiff believes and avers, that at all times material, Defendant FRAZIER held himself out to Plaintiff and the public as specializing in the field of cardiology and cardiovascular diseases.

3. At all times material, Defendant, NEIL J. HART, M.D., (hereinafter referred to as "HART") was and is an adult individual licensed to practice medicine within the Commonwealth of Pennsylvania with his principal office at 420 East North Avenue, Suite 202, Pittsburgh, Allegheny County, Pennsylvania 15212. Plaintiff believes and avers, that at all times material, Defendant HART held himself out to Plaintiff and the public as specializing in the field of cardiology and cardiovascular diseases.

4. At all times material, Defendant, JAMES T. HOPKINS, M.D., (hereinafter referred to as "HOPKINS") was and is an adult individual licensed to practice medicine with the Commonwealth of Pennsylvania with his principal office at 420 East North Avenue, Suite 202, Pittsburgh, Allegheny County, Pennsylvania 15212. Plaintiff believes and avers, that at all times material, Defendant HOPKINS held himself out to Plaintiff and the public as specializing in the field of cardiology and cardiovascular diseases. Plaintiff additionally believes and avers that Defendants FRAZIER, HART and HOPKINS, at all times material, had an office located at 1025 Washington Trust Building, Washington, Washington County, Pennsylvania.

5. At all times material, Defendant, LOUIS C. TRIPOLI, M.D., (hereinafter referred to as "TRIPOLI") was and is an adult individual licensed to practice medicine within the Commonwealth of Pennsylvania with his principal office located at 90 West Chestnut Street, Millcraft Center, Washington, Washington County, Pennsylvania 15301. Plaintiff believes and avers that Defendant TRIPOLI at all times held himself out to Plaintiff and the public as specializing in the field of internal medicine.

6. Plaintiff believes and avers that she has suffered from juvenile-onset diabetes since the age of nine and until the present date, has experienced several complications as a result of said diabetic condition.

7. Plaintiff believes and avers that in December 1988,

she began to experience pain in her arms and back with her heart beating at a rapid pace. As such, Plaintiff presented herself to a certain physician in the Washington area wherein it was determined that Plaintiff should be admitted to a certain hospital in Washington, Pennsylvania wherein a diagnosis of Paroxysmal Ventricular Tachycardia was made. Plaintiff believes and avers that several days later, she was transferred to a certain hospital in the Pittsburgh area wherein she was referred to and came under the care of Defendants FRAZIER, HART and HOPKINS.

8. Plaintiff believes and avers that on or about January 5, 1989, Defendant HART performed a coronary arteriographic study wherein a diagnosis of severe coronary atherosclerotic heart disease and mild-moderate left ventricular dysfunction was rendered.

9. Plaintiff believes and avers that as a result of the diagnostic testing performed upon her and the prescription of certain medications to determine which medication would best treat her heart condition, Plaintiff was prescribed Quinidine 300 mg. Q6H and Mexiletine 150 mg. Q8H, as well as other medications for her heart and thyroid conditions. Plaintiff believes and avers that said medications were prescribed and/or approved of by Defendants FRAZIER and HART.

10. Plaintiff believes and avers that at no time while she was an inpatient at a certain Pittsburgh-area hospital, in January 1989, was she informed by Defendants FRAZIER or HART of any risks or complications associated with Plaintiff's ingestion

of Quinidine for her heart condition. Plaintiff believes and avers that at no time while under the care and treatment of Defendants FRAZIER, HART or HOPKINS, was she informed of any type of risk or complication associated with taking Quinidine for her heart condition. Plaintiff believes and avers she was informed of the risks and complications associated with the diagnostic testing performed upon her by Defendant HART but was not informed by any of the Defendants of the risks and complications associated with Quinidine.

11. Plaintiff believes and avers that as of January 1989 it was known throughout the fields of dermatology and cardiology that Quinidine, a widely-used drug in the control of ventricular arrhythmias, was associated with a diverse assortment of adverse reactions. Plaintiff believes and avers that as of January 1989, it was known within the medical community that reported reactions to Quinidine included rashes or pruritus as well as photo-sensitive Livedo Reticularis. Plaintiff believes and avers that said complications as listed above have been discussed in various medical journals which were available to the Defendants in this case.

12. Plaintiff believes and avers that subsequent to her discharge from the Pittsburgh-area hospital in January 1989, she resumed care with Defendant TRIPOLI as Defendant TRIPOLI would continue to monitor her diabetic condition, with associated complications as well as her cardiac condition.

13. Plaintiff believes and avers that in March 1989,

Plaintiff was examined by Defendant HOPKINS wherein Plaintiff's medication of Quinidine was changed to a different form of Quinidine, known as Quinidine Gluconate and in addition, Plaintiff's dosage of Quinidine was increased. Plaintiff believes and avers that at no time during said examination did Defendant HOPKINS inform or advise Plaintiff of the risks and possible complications associated with Quinidine or its derivative and as such, Plaintiff continued to take said medication without fear of risk or complication.

14. Plaintiff believes and avers that in June 1990, but prior to June 16, 1990, Plaintiff was sitting out in the sun with short pants for approximately thirty to forty-five minutes. Plaintiff then went back into her home with no apparent injury or problem with her legs at that time. Plaintiff avers that the next day when she woke up, both of her lower extremities were experiencing mild distress. Subsequently, Plaintiff began to experience streaks of black, blue and silver on her lower extremities beginning from her ankles to her thighs on both lower extremities. It was at this time that Plaintiff telephoned Defendant TRIPOLI wherein she was instructed to present herself to the Emergency Room of a certain Washington-area hospital.

15. As such, Plaintiff believes and avers that on or about June 16, 1990, she presented herself to the Emergency Room of a certain Washington-area hospital with a rash and red and blue lesions on her lower extremities. Plaintiff believes that she was discharged from the Emergency Room on said date to follow-up with

a dermatologist.

16. Plaintiff believes and avers that on or about June 22, 1990, she presented herself to a certain dermatologist in the Washington, Pennsylvania area wherein she presented with Reticulated Violaceous Macular eruption with blanching centers occurring after sun exposure. Said eruptions were present over the extensor lower legs and thighs. Plaintiff believes and avers that the diagnosis at said time was Livedo Reticularis.

17. Plaintiff believes and avers that from June 22, 1990 through July 8, 1990, the rash or discoloration in her lower extremities began to change and Plaintiff's lower extremities began to ulcerate and become extremely painful. As a result of the severe pain, Plaintiff presented herself to the Emergency Room of a certain Washington-area hospital on July 8, 1990 and was admitted into said hospital at that time. Plaintiff believes and avers that at the time that during her admission at the certain Washington-area hospital, she was informed by a physician at the hospital and informed by her dermatologist that the rash and ulcerations were caused by the Quinidine she was taking and at this time, Plaintiff was informed of past cases of Quinidine induced photo-sensitive Livedo Reticularis-like eruptions.

18. Plaintiff believes and avers that during her admission of July 8, 1990 to the certain Washington-area hospital, it was decided to discontinue the dosage of Quinidine. In addition, Plaintiff continued to experience severe pain and continued skin breakdown and ulcerations of both lower extremities.

19. Plaintiff believes and avers that on July 18, 1990, she was discharged from the Washington-area hospital and referred to the certain Pittsburgh-area hospital referred to above for Hyperbaric oxygen treatments and other treatments for the skin breakdown of her lower extremities. Plaintiff believes that at the time of her discharge, the prognosis regarding her legs was undecided and uncertain.

20. Plaintiff believes and avers that she was transferred to Allegheny General Hospital for medical care and treatment which consisted of Hyperbaric oxygen therapy, debridement and prescription of antibiotics. Plaintiff was then subsequently discharged from the Pittsburgh-area hospital.

21. Plaintiff believes and avers that her condition and the ulcerations and lesions on her lower extremities got worse and as such, Plaintiff presented herself back to the Washington-area hospital on or about August 21, 1990 in mild Diabetic Ketoacidosis. However, Plaintiff believes and avers that upon her admission to the certain Washington-area hospital, Plaintiff was not placed on antibiotics until on or about September 14, 1990. Plaintiff believes and avers that Defendant TRIPOLI was her attending physician during her admission to the certain Washington-area hospital from August 21, 1990 through the date of discharge on September 26, 1990.

22. Plaintiff believes and avers that during her admission of August 21, 1990, the condition of her lower extremities continued to deteriorate and that Plaintiff was

receiving no relief from her condition through the care and treatment rendered at the Washington-area hospital.

23. Plaintiff believes and avers that since she was receiving no relief from her condition through the care and treatment rendered to her at the Washington-area hospital, Plaintiff requested transfer to a hospital in the Cleveland, Ohio area wherein she was admitted on September 26, 1990 and discharged on October 24, 1990. Plaintiff believes and avers that her principal diagnosis upon admission to the Cleveland-area hospital was bilateral severe ulcerative lesions of the lower extremities and necrotizing gangrene bilateral, of both lower legs.

24. Plaintiff believes and avers that on or about September 28, 1990 she underwent an operative procedure known as a bilateral debridement of extensive necrosis of leg ulcers. Plaintiff believes that said operative procedure was performed to control the infection in her lower extremities.

25. Plaintiff believes and avers that the condition of her lower legs became resistant to therapy and, as such, since Plaintiff was thereafter informed that her only option was amputations, on or about October 4, 1990, Plaintiff underwent surgery for bilateral above-the-knee amputations. Plaintiff believes and avers that had she been transferred or referred to the Cleveland-area hospital earlier than September 26, 1990, the amputation of Plaintiff's lower extremities would not have been necessary even though her lower extremities would have never been the same as prior to June 1990.

26. As a direct and proximate result of the Defendants' negligent, careless and/or reckless conduct as more fully set forth above and below, Plaintiff has sustained the following injuries and damages all of which may be continuing in nature and character:

a. Plaintiff sustained a loss of her lower extremities through bilateral above-the-knee amputations;

b. Plaintiff had to undergo severe and excruciating pain, suffering and inconvenience as a result of the lesions or ulcerations which formed upon her lower extremities from June 16, 1990 through October 4, 1990;

c. Plaintiff has sustained severe emotional harm, trauma, distress, anxiety, embarrassment and humiliation;

d. Plaintiff has suffered an impairment to her earning capacity or potential earning capacity;

e. Plaintiff has had to be fit and has received bilateral above-the-knee prostheses thereby requiring her to expend large sums of money on said prostheses as well as incurring large amounts of medical bills as a result of the medical care and treatment she received from June 16, 1990 through the present date;

f. Plaintiff has been and will be required to undergo physical therapy in the use of her above-the-knee prostheses;

g. Plaintiff has been subjected to medications and medical care and medical treatment and may be subjected in the future to medications and medical treatment;

h. Plaintiff has sustained a substantial impairment in the performance of her daily activities and of course, Plaintiff is unable to perform most, if not all, of the activities that she was able to perform prior to June 1990;

i. Plaintiff's ability to enjoy life has been substantially impaired and will remain substantially impaired the remainder of her life;

j. Plaintiff has suffered from the appearance of the conditions of her extremities;

k. Plaintiff sustained a substantial interference with family relationships and said interference may continue in the future; and

l. Plaintiff sustained substantial pain, suffering and inconvenience as a result of the bilateral above-the-knee amputations.

COUNT I -- TORT
CATHERINE I. WILSON, Plaintiff v. JOHN E. FRAZIER II, M.D. NEIL J. HART, M.D. and JAMES T. HOPKINS, M.D., Defendants

27. The allegations set forth in Paragraphs 1 through 26 above are hereby incorporated by reference into Count I of this Complaint.

28. At all times material, Plaintiff believes and avers that these Defendants were under a duty of care to advise Plaintiff of all risks, complications or consequences with the prescription of Quinidine or its derivative, which was prescribed by the Defendants in January 1989.

29. Plaintiff believes and avers that said duty of care requires that the Defendants advise Plaintiff of all risks, complications and consequences associated with the prescription of Quinidine since said medication has been found to induce adverse reactions in patients such as Plaintiff as well as cause photo-sensitive Livedo Reticularis.

30. Plaintiff, at all times material, has the legal right to make an informed decision as to whether to take the

medication of Quinidine, once she is informed of all the risks and complications associated with said drug or in fact, Plaintiff has the right to receive all information necessary for her to take the necessary precautions so that said risks and complications associated with Quinidine could be avoided.

31. As such, Defendants failed to gain the informed consent of Plaintiff when Defendants failed to advise Plaintiff of all the risks, complications and consequences with taking Quinidine or its derivative. Accordingly, Plaintiff believes and avers that Defendants committed a battery upon her as Defendants did not have the proper authority to prescribe said medication to her.

32. As a direct and proximate result of the Defendants failure to gain Plaintiff's informed consent and as a result of Defendants' battery upon Plaintiff, Plaintiff has sustained those injuries and damages as set forth in Paragraph 26 above.

WHEREFORE, Plaintiff demands judgment in her favor against the Defendants in an amount in excess of $20,000.00 and in an amount in excess of the jurisdiction of the Arbitration Division of the Court, plus costs.

COUNT II -- TORT
CATHERINE I. WILSON, Plaintiff v. JOHN E. FRAZIER II, M.D. NEIL J. HART, M.D. and JAMES T. HOPKINS, M.D., Defendants

33. The allegations set forth in Paragraphs 1 through 32 above are hereby incorporated by reference into Count II of this Complaint.

34. Plaintiff believes and avers that at all times material, Defendants were under a duty to exercise reasonable care in the medical care and treatment of Plaintiff under the circumstances. In addition, Plaintiff avers that the standard of care in the medical community required that Defendants have knowledge of the known risks and complications associated with the prescription of Quinidine or its derivative to Plaintiff, especially given Plaintiff's vascular condition. In addition, Defendants were under a duty and the standards in the medical community dictate that Defendants inform Plaintiff of the known risks and complications associated with the prescription of Quinidine or its derivative at the time prescribing said medication to Plaintiff.

35. Plaintiff believes and avers that Defendants were negligent, careless and/or reckless for their conduct as set forth above and as more fully set forth in the following particulars:

a. In failing to gain Plaintiff's informed consent prior to prescribing Quinidine or its derivative;

b. In failing to know or understand the known risks and complications associated with the prescription of the drug Quinidine or its derivative;

c. In failing to perform research or in failing to read journals or periodicals which discussed or provided information to the medical community of the known risks and complications associated with Quinidine and its derivative;

d. In failing to determine whether each or any of the other Defendants informed Plaintiff of the known risks and complications associated with Quinidine or its derivative;

e. In failing to exercise the required standards of care for the care and treatment of Plaintiff under the circumstances;

f. In failing to exercise the required standards of care for physicians with Defendants' background and expertise;

g. In failing to know or to recognize the required standards of care in the medical community for the care and treatment or prescription of Quinidine or its derivative to Plaintiff under the circumstances;

h. In failing to know, understand or recognize the effect of Plaintiff's vascular condition on the known risks and complications associated with Quinidine or its derivative;

i. In otherwise failing to exercise that degree of care due and owing under the circumstances; and

j. By increasing the risk of harm to Plaintiff which actually befell her.

36. Plaintiff believes and avers that Defendants' failure to inform her of the known risks and complications associated with Quinidine or its derivative substantially increased the risk of harm that would befall Plaintiff and which actually did occur.

37. As a direct and proximate result of the Defendants' conduct, Plaintiff has sustained those injuries and damages as set forth in Paragraph 26 above.

WHEREFORE, Plaintiff demands judgment in her favor against the Defendants in an amount in excess of $20,000.00 and in an amount in excess of the jurisdiction of the Arbitration Division of the Court, plus costs.

COUNT III -- TORT
CATHERINE I. WILSON, Plaintiff v. LOUIS C. TRIPOLI, M.D., Defendant

38. The allegations set forth in Paragraphs 1 through 37 above are hereby incorporated by reference into Count III of this Complaint.

39. At all times material, Defendant TRIPOLI was under a duty to exercise reasonable care in the medical care and treatment of Plaintiff under the circumstances. In addition, at all times material, Defendant TRIPOLI was under a duty to render medical care and treatment within the standards of care within the medical community.

40. Plaintiff believes and avers that Defendant TRIPOLI deviated from the acceptable standards of medical care in the community, inter alia, for failing to properly attend Plaintiff's condition as of August 21, 1990 through September 26, 1990 wherein Plaintiff was finally transferred and referred to a hospital in the Cleveland area which was properly qualified and equipped to provide Plaintiff with the required medical care and treatment for her condition.

41. Plaintiff believes and avers that Defendant TRIPOLI deviated from the acceptable standards of care in the medical community and was otherwise negligent, as set forth above and as set forth more fully in the following particulars:

a. In failing to adhere to the required standards of care in the medical community for Plaintiff under the circumstances;

b. In failing to know or realize the appropriate standards of care in the medical community for the medical care and treatment of Plaintiff under the circumstances;

c. In failing to administer adequate and proper antibiotic therapy on or about August 21, 1990;

d. In failing to know or realize that adequate and proper antibiotic therapy had not been administered on August 21, 1990;

e. In failing to refer Plaintiff or transfer Plaintiff to another hospital facility qualified and equipped to provide Plaintiff with the required medical care and treatment for her condition;

f. In permitting gangrene to set in to Plaintiff's lower extremities;

g. In failing to advise Plaintiff of the known risks and complications associated with Quinidine or its derivative;

h. In failing to exercise that degree of care due and owing to Plaintiff under the circumstances;

i. In failing to determine whether Plaintiff's cardiologists, the other Defendants in this matter, properly advised Plaintiff of the known risks and complications associated with Quinidine or its derivative;

j. In failing to treat and/or properly and adequately treat or refer Plaintiff for treatment for the infections or ulcerations of her lower extremities from August 21, 1990 through September 14, 1990;

k. In failing to timely treat and/or properly and adequately treat or timely refer Plaintiff for treatment for the infections or ulcerations of her lower extremities from August 21, 1990 through September 14, 1990;

l. By increasing the risk of harm which actually befell Plaintiff;

m. In delaying the referral or transfer of Plaintiff to another hospital facility qualified or equipped to render appropriate medical care and treatment to Plaintiff for her condition; and

n. In delaying Plaintiff's treatment or in inadequately treating Plaintiff's condition such that a worsened condition, gangrene, protracted recovery and subsequent extended care, treatment and surgery by another physician resulted.

42. Plaintiff believes and avers that Defendant TRIPOLI's conduct increased the risk of harm for injuries which Plaintiff actually sustained.

43. As a direct and proximate result of Defendant's conduct, Plaintiff has sustained those injuries and damages as set forth in Paragraph 26 above.

WHEREFORE, Plaintiff demands judgment in her favor against the Defendants in an amount in excess of $20,000.00 and in an amount in excess of the jurisdiction of the Arbitration Division of the Court, plus costs.

Respectfully submitted,

Bruce S. Gelman

BRUCE S. GELMAN, ESQUIRE

Janet S. Livengood

JANET S. LIVENGOOD, ESQUIRE
Attorneys for Plaintiff

VERIFICATION

Now comes Plaintiff, CATHERINE I. WILSON in the civil action at which the foregoing document is intended to be filed of public record, who verifies that the facts set forth in the foregoing COMPLAINT IN CIVIL ACTION are true and correct to the best of her knowledge, information and belief. This Verification is made subject to the penalties of 18 Pa.C.S. Section 4904, relating to unsworn falsification to authorities, which provides for criminal penalties if a person with intent to mislead makes a written false statement which he does not believe to be true.

9-18-1992
DATE

Catherine I Wilson
CATHERINE I. WILSON

No. 99C3155
United States District Court, N.D. Illinois, Eastern Division

Skolnick v. Correctional Medical Services, Inc.

132 F. Supp. 2d 1116 (N.D. Ill. 2001)
Decided Mar 15, 2001

No. 99C3155.

March 15, 2001.

OPINION AND ORDER

CHARLES R. NOROLE, SR. District Judge

Before the court are: (1) the motion of Defendants, Correctional Medical Services ("CMS"), Spectrum Healthcare Services, Richard Miles, and Louis Tripoli,[1] for summary judgment on Plaintiff's claims of defamation per se [29-1]; and (2) Plaintiff's motion to strike Defendants' response to Plaintiff's Local Rule 56.1(b)(3) responsive statement of facts [45-1]. For the following reasons, Defendants' motion for summary judgment is granted and Plaintiff's motion to strike is denied as moot.

[1] Where appropriate, the court refers to these Defendants collectively as the "CMS Defendants," or simply as "Defendants." Plaintiff has dismissed Imaging Diagnostic Systems and Richard Grable from this suit.

I. BACKGROUND

The short version of this diversity case is that Plaintiff, Andrew Skolnick, is an investigative journalist who wrote or contributed to several articles that were critical of healthcare in prisons in general, and of CMS in particular. The CMS Defendants, in turn, made several written responses to these articles. Not to be outdone in this water pressure contest, Skolnick sued the CMS Defendants, claiming that their responses defamed him and interfered with his business interests. Many of the underlying facts are disputed, but the material ones are not.

From November 1987 until November 1998, Skolnick was an associate editor for the Journal of the American Medical Association ("JAMA"). Skolnick's primary job at JAMA was to write approximately twenty-four stories per year for the "Medical News and Perspectives" section of JAMA. In 1997, upon the recommendation of his editor at JAMA, Marcia Goldsmith, Skolnick was selected as a Rosalynn Carter Fellow for Mental Health Journalism. As a Rosalynn Carter Fellow, Skolnick was to investigate and submit articles about medical and mental health issues in prisons.

The CMS Defendants are engaged in the business of providing prison healthcare services. In 1998, Skolnick began investigating the practices of CMS and allegations of its use of impaired or disciplined physicians in prisons. During his investigation, Skolnick consistently identified himself to CMS as an. associate editor for JAMA and a Rosalynn Carter fellow. Skolnick claims he also told CMS he was working for other publications, but admits he did not identify any such publication. By mid-August 1998, Skolnick ended his communications with CMS.

Based on his research, Skolnick wrote two articles for JAMA: "Prison Deaths Spotlight How Boards Handle Impaired, Disciplined Physicians;" and "Critics Denounce Staffing Jails and Prisons With Physicians Convicted of Misconduct" (hereinafter

the "JAMA articles"). JAMA planned to publish these articles in September 1998, but delayed publication until its October 28, 1998 issue.

In mid-August 1998, reporters William Allen and Kim Bell of the St. Louis Post-Dispatch asked Skolnick to assist them in completing a special report on prison healthcare. Using personal time, Skolnick went to St. Louis on September 12, 1998 to contribute to the report. Skolnick, along with Allen and Bell, wrote or contributed to three articles that were published in the September 27, 1998 edition of the paper: "Physicians with troubled pasts have found work behind bars;" "Two key posts in Alabama were filled by doctors with checkered histories;" and "Prisoner, doctor who treated him, both had drug arrests" (hereinafter the "Post-Dispatch articles"). The Post-Dispatch articles, which were critical of CMS, identified Skolnick as an author, special contributor, and Rosalynn Carter Fellow.

After publication of the Post-Dispatch articles, CMS became aware that JAMA was planning to publish the JAMA articles. On October 26, 1998, the chief medical officer of CMS, Louis Tripoli, wrote the following letter to the chief editor of JAMA:

> I am the Chief Medical Officer at Correctional Medical Services, Inc., the nation's leading provider of healthcare services in correctional facilities, and have been a loyal member of the AMA for my entire professional career. It has come to our attention that JAMA's October 28, 1998 edition contains articles regarding the provision of medical services by our company. If that is the case, CMS requests the opportunity to provide further input and respond to any assertions to be made regarding our company and medical practices.

We make this request for three reasons. ***First,*** we have reason to believe that much of the background "facts" and assertions recently provided to journalists regarding CMS have been provided by plaintiff lawyers adverse to CMS as part of a campaign seeking to advance their litigation and financial interest by generating unfair and negative publicity regarding CMS and its healthcare professionals, many of whom are also AMA members. We are aware that plaintiff lawyers adverse to CMS have provided information to Andrew Skolnick of JAMA. We are certain that JAMA would not wish to be used by persons with ulterior agendas as a vehicle for the publication of inaccurate assertions regarding healthcare professionals.

Second, we have reason to believe that many of the assertions regarding CMS that may be published in JAMA have resulted from an "investigation" that included the use of questionable reporting tactics. Specifically, Andrew Skolnick repeatedly used the name of JAMA and, by implication the American Medical Association's reputation, when gathering information. However, Mr. Skolnick's stories first appeared, with his byline, in the *St. Louis Post-Dispatch* (September 27). Mr. Skolnick never mentioned to us that he was working on behalf of the Post-Dispatch. We trust that JAMA would not condone or reward the misleading use of the AMA's name. We would like the opportunity to discuss these issues with you further prior to any publication of assertions regarding CMS business or medical practices.

> ***Third,*** our reputation as a healthcare provider and the reputations of the healthcare professionals who work for us are of central concern to us. The publication of inaccurate assertions could result in substantial personal and financial damage to the parties involved. We believe that standards of professional responsibility and courtesy between medical doctors and healthcare professionals warrant the opportunity for us to reply and respond to any purportedly negative factual assertions regarding our practices prior to publication. We also believe that the separate journalistic standards of fairness, balance and accuracy require such an opportunity.
>
> Accordingly, we request that prior to the publication of any assertions regarding CMS by JAMA, we be provided with an opportunity to be heard and to respond to any assertions regarding our company. We have no doubt that JAMA will provide us with that opportunity. Please feel free to call me directly with any questions. I look forward to hearing from you.

(Def.'s Local Rule 56.1 Ex.10.)

On November 3, 1998, JAMA fired Skolnick. JAMA wrote a memo stating that Skolnick was terminated, in part, for contributing to the Post-Dispatch articles without informing his supervisor. Skolnick disputes this, claiming that JAMA allows its reporters to write about medical issues for non-medical publications. Skolnick alleges that the real reason JAMA fired him was negative reaction to the Post-Dispatch articles.

On November 20, 1998, Thomas Yanucci, an attorney representing CMS, sent a twenty-one page letter about the Post-Dispatch articles to the managing editor of the St. Louis Post-Dispatch. Yanucci's letter stated, in relevant part:

IV. The Newsgathering Tactics Employed by the Reporters Cast Considerable Doubt On Their Objectivity And Fairness And Establish Malice Toward CMS.

The reporters involved in the publication of the special report have employed tactics that have been repeatedly condemned by responsible media. Each of these actions is independent evidence of malice towards CMS, warranting serious reevaluation of the entire piece and proper steps going forward to guarantee fair treatment of CMS.

Failure to disclose reporter's identity. On February 27, 1998, CMS Communications Director Susan Adams received a telephone call from Andrew Skolnick. Introducing himself, Mr. Skolnick stated that he was working for the Journal of the American Medical Association ("JAMA"). Mr. Skolnick told Ms. Adams that he was working on an article for JAMA.

Based on Mr. Skolnick's representations, Ms. Adams agreed to meet Mr. Skolnick in Alabama and provide him with access to various facilities at which CMS provides healthcare services. During that meeting and tour of CMS facilities, Mr. Skolnick presented a business card identifying himself as the "Associate Editor" of JAMA. At no time did Mr. Skolnick inform Ms. Adams — or anyone else at CMS — that he was writing for or affiliated in any way with the *St. Louis Post-Dispatch*. CMS did not learn that Mr. Skolnick was writing for the *St. Louis Post-Dispatch* until his articles appeared in the September 27, 1998 edition of the paper.

CMS disagrees with your assertion that Mr. Skolnick "was completely up front" with CMS because CMS was aware of the "issues" he was working on. JAMA certainly did not think that Mr. Skolnick was "up front" about its role in the preparation of the special section; it terminated Mr. Skolnick's employment shortly after his role in the special report was brought to light. Mr. Skolnick deliberately withheld the fact that — in addition to writing JAMA — he was sharing information with the *Post-Dispatch* reporters and contributing stories to their special report. There can be no good reason for withholding this information from CMS. Such deliberately deceptive conduct is further evidence of malice and bad faith toward CMS, the common target of Mr. Skolnick and the Post-Dispatch's journalistic efforts. There can be no justification for a reporter deliberately misleading the subject of a story.

While the editors and management at the Post-Dispatch have largely ignored CMS's concerns, other publishers have responded to CMS's concerns. During both of your meetings, Mr. Miles explained how Andrew Skolnick — a contributing author whose articles appeared in your paper "[s]pecial to the *Post-Dispatch*" — told CMS employees that he was working on an article for the Journal of American Medicine ("JAMA") when in fact he was writing for the *Post-Dispatch*. Mr. Miles pointed out the serious issues raised by a reporter misrepresenting his identity to the subject of a story. When CMS raised these issues with JAMA, it took immediate corrective action. Confronted with the same facts about Mr. Skolnick's conduct and his role in the preparation of the special report, JAMA immediately terminated his employment. The fact that JAMA — a third party that has no vested interest in defending the special report — took such decisive action validates CMS's concerns about the newsgathering process employed by the *Post-Dispatch* and casts serious doubt on the supervision of the reporters involved in the preparation of the special report.

By this letter, we are putting you — and the Post-Dispatch — on further notice that CMS views Mr. Skolnick's conduct as dishonest, fraudulent and deceitful. We repeat our request that the *Post-Dispatch* clearly instruct all of its reporters, correspondents and contributing authors to clearly identify themselves as working for the *Post-Dispatch*, when contacting CMS and its employees.

(Def.'s Local Rule 56.1 Ex. 14, pp. 15-16.)

On March 15, 1999, Defendant Richard Miles sent a package of materials to Jim Whittum, a judge in the Missouri Associated Press Managing Editors

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News Writing Contest, in which the Post-Dispatch articles were entered. Miles' cover letter stated that the enclosed materials would demonstrate that the Post-Dispatch articles fell below the contest's journalistic standards for excellence. One of the enclosures was CMS' eighteen page response to the Post-Dispatch articles, which contained the following:

> Allegation [from the Post-Dispatch articles]: " *An internationally renowned expert on forensic medicine and pathology from the University of Chicago called that report a 'whitewash' and said Moore's death was 'a homicide resulting from criminal negligence.'" (Allegation references documents in the death of Calvin Moore.)*
>
> [CMS' response]: ***False*** . The article does not reveal that the physician cited, Dr. Robert Kirschner, was paid to be an expert witness for the plaintiff in this case. In contrast, the coroner's autopsy — which stated that the inmate's death was from *natural causes* — was performed by an independent state medical officer, who was NOT paid by either side to be a professional witness. The newspaper failed to mention these critical facts,
>
> . . . .
>
> Allegation [from the Post-Dispatch articles]: " *Diseases don't respect bars. Each year in the United States, 12 million inmates return to society, bringing with them a broad range of diseases that are often infectious."*
>
> . . . .
>
> [CMS' response]: The *Post-Dispatch* attempts to alarm readers by reporting that "12 million inmates return to society" each year. However, it is critical to note that, in the same article, the *Post-Dispatch* also reports that the nation's federal, state, and local criminal justice systems house approximately 1.7 million inmates. This contradiction evidences the *Post-Dispatch's* selective, arbitrary, and illogical use of facts.
>
> . . . .
>
> [CMS' summary of the Post-Dispatch articles]: The reporters' thesis is flawed, their statements are inaccurate, and the tone is sensationalistic. In short, their articles do a terrible disservice to the physicians, nurses, and other healthcare professionals who care for inmate patients in extremely difficult and challenging environments. They are dedicated and hardworking people who do not deserve to be vilified by reporters who disregard the truth in pursuit of journalistic accolades. While these healthcare professionals have been unjustly maligned, the truth is the real victim.

(Def.'s Local Rule 56.1 Ex. 12(A)(V) pp. 14, 18, 19.)

On May 12, 1999, Skolnick filed suit for tortious interference with prospective economic advantage under Illinois law. Skolnick later amended his complaint to allege that the above quoted material from the Tripoli, Yanucci, and Miles letters is defamatory per se under Illinois law. The CMS Defendants moved for summary judgment on all claims, and moved to stay discovery during the briefing. The court granted the motion to stay discovery, and limited the parties' briefing to the defamation per se claims.

Thus, the primary issue before the court is whether the three letters defamed Skolnick under Illinois law. Defendants argue that the quoted material is not defamatory per se, is capable of an innocent construction, and is non-actionable opinion. Skolnick agrees that Illinois law governs this dispute, but takes the opposite view on all other legal issues.

II. DISCUSSION

A. Motion to Strike

Local Rule 56.1 outlines the procedure for presenting facts in support of, and in opposition to, motions for summary judgment. Skolnick did not originally file a Local Rule 56.1(b)(3) response with his brief in opposition to the summary judgment motion. The court granted him leave to file an untimely 56.1(b)(3) response, in which he did not raise any additional facts. Defendants filed a response thereto, which Skolnick moves to strike.

The points Skolnick raises in his motion to strike are well taken. Defendants' response to his 56.1(b)(3) statement was unnecessary and improper. Nevertheless, the court did not consider Defendants' response in ruling on the summary judgment motion. Accordingly, Skolnick's motion to strike is denied as moot. That said, the court turns to the motion for summary judgment.

B. Standards for summary judgment

Summary judgment is permissible when "there is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). Under Illinois law, the issues presented in this case, defamation per se, the innocent construction doctrine, and statements of opinion, are questions of law that are properly decided by the court. See Bryson v. News America Publications, Inc., 672 N.E.2d 1207, 1215 (Ill. 1996) (whether statement is capable of innocent construction is a question of law); Moriarty v. Greene, 732 N.E.2d 730, 740 (Ill.App.Ct. 2000) (whether statement is protected opinion is a question of law); Miller v. Danville Elks Lodge 332, 569 N.E.2d 1160, 1164 (Ill.App.Ct. 1991) (whether statement is defamatory per se is a question of law).

C. Defamation per se

The court first discusses the law of defamation, and then analyzes each of the letters. Defamation allows a person to recover for harm to his or her reputation caused by false allegations of fact. Hopewell v. Vitullo, 701 N.E.2d 99, 102 (Ill.App.Ct. 1998). "A statement is considered defamatory if it tends to cause such harm to the reputation of another that it lowers that person in the eyes of the community or deters third persons from associating with her." Bryson, 672 N.E.2d at 1214. "To prove a claim of defamation, a plaintiff must show that the defendant made a false statement concerning plaintiff, that there was an unprivileged publication of the defamatory statement to a third party by defendant, and that plaintiff was damaged." Dubinsky v. United Airlines Master Exec. Council, 708 N.E.2d 441, 446-47 (Ill.App.Ct. 1999).

"Defamatory statements may be actionable per se or actionable per quod." Id.; see also Pope v. Chronicle Publishing Co., 95 F.3d 607, 613 (7th Cir. 1996) (analyzing Illinois law). "A publication is defamatory per se if it is so obviously and naturally harmful to the person to whom it refers that a showing of special damages is unnecessary and extrinsic facts are not needed to explain it." Dubinsky, 708 N.E.2d at 447. By contrast, "[a] claim for defamation per quod requires the plaintiff to allege both extrinsic facts to establish that the statement is defamatory and special damages with particularity." Id. In this case, Skolnick is proceeding solely on a theory of defamation per se.

Illinois common law recognizes four categories of defamation per se: "(1) words that impute the commission of a criminal offense; (2) words that impute infection with a loathsome communicable disease; (3) words that impute an inability to

perform or want of integrity in the discharge of duties of office or employment; or (4) words that prejudice a party, or impute a lack of ability, in his or her trade." Bryson, 672 N.E.2d at 1214-15. Skolnick focuses on the third and fourth categories, claiming that the Tripoli, Miles and Yanucci letters falsely impute that Skolnick lacks integrity as a journalist, and prejudice him in his occupation.

Illinois law recognizes several defenses to defamation liability, two of which are at issue in this case — the innocent construction doctrine and expressions of opinion.

1. Innocent Construction:

"Even if a statement falls into one of the recognized categories of words that are actionable per se, it will not be found actionable per se if it is reasonably capable of an innocent construction." Bryson, 672 N.E.2d at 1215. The innocent construction rule requires the court to interpret the alleged defamation in context and give the words their natural and obvious implications and meanings. Id. If, as so construed, "a statement `may reasonably be innocently interpreted or reasonably be interpreted as referring to someone other than the plaintiff, it cannot be actionable per se.'" Id. (quoting Chapski v. Copley Press, 442 N.E.2d 195, 199 (Ill. 1982)). There is no balancing of reasonable constructions. Dubinsky, 708 N.E.2d at 447. If a statement taken in context is reasonably capable of a non-defamatory interpretation, the court should so construe it. Id. This higher standard is necessary because of the presumption of damages in per se actions. Id.

An offshoot of the innocent construction rule is that the court should, if the context permits, limit statements about the plaintiff to a particular setting or single instance, so that the statements do not generally impugn the plaintiff's fitness for his or her chosen occupation. Anderson v. Vanden Dorpel, 667 N.E.2d 1296, 1302-03 (Ill. 1996); Dunlap v. Alcuin Montessori School, 698 N.E.2d 574, 581 (Ill.App. Ct. 1998). But, the Illinois Supreme Court has made it clear that the focus of the inquiry is on the context of the alleged defamation, rather than a simple determination of whether the defamation relates to a single instance. Costello v. Capital Cities Communication, Inc., 532 N.E.2d 790, 795-96 (Ill. 1988). A statement is actionable if, when taken in context, it generally impugns a person's fitness for his or her profession, even if the statement is limited to a particular setting or single instance.See id. (finding a statement directed to a single instance actionable because it generally impugned the plaintiff s fitness for office);compare Anderson, 667 N.E.2d at 1302-03 (finding an innocent construction for statements made in reference to the plaintiffs past performance in a single position, so that the statements did not pertain to the plaintiffs general fitness for a different employer).

2. Protected Opinion:

There is an obvious tension between freedom of speech and defamation.See e.g., Sullivan v. Conway, 157 F.3d 1092, 1098 (7th Cir. 1998) (noting how defamation suits can inhibit "the free and frank exchange of ideas, facts, and opinions. . . ."); Haynes v. Alfred A. Knopf, Inc., 8 F.3d 1222, 1224 (7th Cir. 1993) (analyzing "difficult issues at the intersection of tort law and freedom of the press."). Therein lies the irony. Skolnick, being an investigative journalist, is the last person one would expect as a plaintiff in a defamation case. His very livelihood depends on the free and frank exchange of facts and ideas. For him to wish to stifle the exchange of facts and ideas on prison healthcare is puzzling, especially where his work represents only one view of the subject, and has stimulated public debate on the topic. See Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J. dissenting) ("But when men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade in ideas — that the best test of truth is

the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out.").

Based on the first amendment to the United States constitution, Illinois law does not impose liability for expressions of opinion that may be considered defamatory per se and are incapable of an innocent construction. See Bryson, 672 N.E.2d at 1219-20 (analyzing Milkovich v. Lorain Journal Co., 497 U.S. 1, 10-23 (1990)). Illinois law on the issue of fact versus opinion largely follows federal constitutional principles. Nevertheless, the analysis begins, and in this case ends, with Illinois law rather than federal constitutional law. As Judge Easterbrook has explained, the court should examine whether state law imposes liability for defamation before venturing into the complexities of federal constitutional defenses to such liability. Underwager v. Salter, 22 F.3d 730, 733 (7th Cir. 1994) (limiting actual malice analysis to Wisconsin law); see also Wilkow v. Forbes, Inc., ___ F.3d ___, ___, 2001 WL 166709, at *3 (7th Cir. Feb. 20, 2001) (limiting fact/opinion analysis to Illinois law).

The parties do not raise the issues of whether Skolnick is a public figure or the CMS Defendants spoke on matters of public concern. See Milkovich, 497 U.S. at 22 (holding that where the plaintiff is a private figure, but the allegation of defamation is connected to a matter of public concern, liability requires some level of fault as defined in Gertz v. Robert Welch, Inc., 418 U.S. 323 (1974)); cf. Dilworth v. Dudley, 75 F.3d 307, 309 (7th Cir. 1996) (analyzing Wisconsin law, but noting that "[b]y publishing your view you invite public criticism and rebuttal; you enter voluntarily into one of the submarkets of ideas and opinions and consent therefore to the rough competition of the marketplace."). The parties do not raise these issues, so the court does not address them further.

The Illinois test to determine whether a statement is non-actionable opinion is a narrow one. Expressions of opinion are protected only when they cannot reasonably be interpreted as stating actual facts about the plaintiff. See Bryson, 672 N.E.2d at 1219-20 (discussing Milkovich, 497 U.S. at 20); see also Restatement (Second) of Torts § 566 (1977) ("A defamatory communication may consist of a statement in the form of an opinion, but a statement of this nature is actionable only if it implies the allegation of undisclosed defamatory facts as the basis for the opinion."). Illinois courts have used a couple of different tests to analyze the issue. The predominant test is based on Ollman v. Evans, 750 F.2d 970 (D.C. Cir. 1984), and consists of four factors: "(1) the precision of the statement; (2) the verifiability of the statement; (3) literary context of the statement; and (4) public and social contexts of the statement." Moriarty, 732 N.E.2d at 740 (citing cases). A slightly different three part test was announced in Hopewell, where the court stated:

> First, we consider whether the language of the statement has a precise and readily understood meaning, while bearing in mind that the first amendment protects overly loose, figurative, rhetorical, or hyperbolic language, which negates the impression that the statement actually presents facts. . . . Second, we consider whether the general tenor of the context in which the statement appears negates the impression that the statement has factual content. . . . Lastly we consider whether the statement is susceptible of being objectively verified as true or false. . . . While this approach considers the context within which the alleged defamatory statement appears, its emphasis is on whether the statement contains an objectively verifiable assertion.

Hopewell, 701 N.E.2d at 103-04 (collecting authority, internal citations omitted).

Neither of these tests is a hard and fast analysis. The emphasis is on the totality of the circumstances, and whether the statement can be reasonably interpreted as stating actual facts or objectively verified as true or false. See Wynne v. Loyola Univ. of Chicago, 741 N.E.2d 669, 676 (Ill.App.Ct. 2000) (citing Hopewell, 701 N.E.2d at 103-04); Moriarty, 732 N.E.2d at 740 (citing Ollman, 750 F.2d 970); Gardner v. Senior Living Systems, Inc., 731 N.E.2d 350, 355 (Ill.App.Ct. 2000) (citing Bryson, 672 N.E.2d at 1220); Dubinsky, 708 N.E.2d at 448; Doherty v. Kahn, 682 N.E.2d 163, 172 (Ill.App.Ct. 1997) (citing Piersall v. Sports Vision of Chicago, 595 N.E.2d 103, 107 (Ill.App.Ct. 1992)). If a statement contains objectively verifiable facts, the question of whether the facts are true or not is normally reserved for the jury. Bryson, 672 N.E.2d at 1220. But, if there's no dispute over their truth or falsity, the court can decide the issue as a matter of law. See Wynne, 741 N.E.2d at 675-76 (citing Hollymatic Corp. v. Daniels Food Equip., Inc., 39 F. Supp.2d 1115, 1118 (N.D. Ill. 1999)). To the extent a statement consists of both verifiable facts and expressions of opinion, the defamation claim fails if the facts are true. See Wynne, 741 N.E.2d at 676 (holding that summary judgment for the defendant was proper where the plaintiff admitted the underlying facts that formed the basis for the defendant's opinion); compare Moriarity, 732 N.E.2d at 740 (holding that the plaintiff stated a claim for defamation by alleging that the defendant falsely attributed an admission to the plaintiff).

It bears emphasis that one cannot avoid liability merely by couching a defamatory statement as an opinion. See Wilkow, ___ F.3d at ___, 2001 WL 166709 at *3 (citing cases). With these principles in mind, the court examines Skolnick's claims.

D. Skolnick's Allegations of Defamation:

Skolnick claims that each of the Tripoli, Miles and Yanucci letters is defamatory per se. The two common threads of Skolnick's allegations are: (1) that the letters falsely state that Skolnick misrepresented himself as working solely for JAMA when he contacted CMS; and (2) that the letters falsely state that Skolnick's reporting of facts in the Post-Dispatch articles was inaccurate. The net effect of both points, according to Skolnick, is that Defendants falsely impute that he lacks skill and integrity as a journalist.

At this point, the court addresses a curious statement in Defendants' opening brief. Defendants state: "For the purposes of this Motion only, [Defendants] are not addressing Skolnick's allegations that they intended to harm him; or that the Tripoli, Miles and Yanucci letter contain false statements." (Defs.' memo. p. 3.) Skolnick jumps on this statement as an admission that the letters contain false statements of fact, which dooms Defendants' innocent construction and opinion arguments. The court does not agree. The statement does not go as far as Skolnick claims. Indeed, Defendants argue, and Skolnick admits, that the material facts stated in the letters — Skolnick telling CMS that he worked for JAMA — are true. (See discussion infra at pp. 15-17; see also Pl.'s Local Rule 56.1(b)(3) Resp. ¶ 27.) Thus, Defendants' statement is of no moment.

1. The Yanucci Letter:

The court first addresses the Yanucci letter because it contains the harshest and most specific criticism of Skolnick. (See supra pp. 5-6 for the relevant text of the Yanucci letter.) According to Skolnick, Yanucci's letter falsely asserts that Skolnick deliberately misled CMS about where his work would appear. Thus, Skolnick argues that the following statements from Yanucci's letter are defamatory: (1) Skolnick "employed tactics that have been repeatedly condemned by responsible media," (2) Skolnick "deliberately withheld the fact that — in addition to writing for JAMA — he was sharing information with the Post-Dispatch . .

.; (3) Skolnick's "deliberately deceptive conduct is further evidence of malice and bad faith toward CMS;" (4) Skolnick "misrepresent[ed] his identity to the subject of a story;" and (5) that "CMS views Skolnick's conduct as dishonest, fraudulent and deceitful." Defendants argue, and the court agrees, that these statements are non-actionable expressions of opinion.

As a preliminary matter, the prefatory language of "CMS views" does not by itself render Yanucci's letter non-actionable. See Wilkow, ___ F.3d at ___, 2001 WL 166709 at *3. That issue aside, the primary question is whether the court can reasonably interpret Yanucci's letter as stating actual facts or objectively verify the statements, while keeping in mind that true statements of fact are not actionable. Gardner, 731 N.E.2d at 355; Hopewell, 701 N.E.2d at 103-04; Wynne, 741 N.E.2d at 675-76;Moriarity, 732 N.E.2d at 740. The Yanucci letter contains an assertion of verifiable fact, i.e., that SkolniCk identified himself as working for JAMA rather than the Post-Dispatch at the time he contacted CMS. This fact is true, and any expression of opinion based on it is not actionable. See Wynne, 741 N.E.2d at 675-76; Moriarity, 732 N.E.2d at 740. Yanucci's letter does nothing more than express CMS' displeasure with seeing Skolnick named as an author and contributor to the Post-Dispatch articles after he told CMS he worked for JAMA. CMS is entitled to form an opinion about that fact without incurring liability.See Wynne, 741 N.E.2d at 676; Moriarity, 732 N.E.2d at 739-40.

Skolnick claims he told CMS that he worked for other publications, so he argues that Yanucci's statements about Skolnick deliberately misleading CMS are false. Skolnick, however, admits he did not mention the names of any other publications to CMS. And, accepting the "other publications" statement as true does not change the outcome. Yanucci's letter is specific to the fact that Skolnick did not mention the Post-Dispatch when he was investigating CMS. Cf. Wynne, 741 N.E.2d at 675-76 (noting that "substantial truth" is a defense to defamation). The somewhat vague reference to "other publications" does not take away CMS' right to comment on the facts it knew — that Skolnick said he worked for JAMA, he did not mention the Post-Dispatch, and he contributed to the Post-Dispatch articles shortly after he ended his contact with CMS. See Wynne, 741 N.E.2d at 676; Moriarity, 732 N.E.2d at 739-40.

Moreover, the context of Yanucci's letter demonstrates that the strong language therein is mere rhetoric and hyperbole. The court must examine the language in context. Language that is loose, figurative, and exaggerated tends to be opinion rather than fact. See Gardner, 731 N.E.2d at 355 (noting that calling the plaintiff "unethical" could not be construed as stating facts, and was non-actionable opinion); Hopewell, 701 N.E.2d at 105 (noting that where a subject is controversial, harsh statements are more likely to be substanceless rhetoric). Yanucci's letter is a response to the editor of a newspaper that published articles highly critical of CMS. Skolnick identified himself to CMS as working for JAMA, and did not tell CMS that his work would also appear in the Post-Dispatch. In this context, Yanucci's statements to the effect that Skolnick was employing "tactics that have been repeatedly condemned by responsible media," misrepresented his identity, and was deliberately deceptive, dishonest, and fraudulent are rhetoric and hyperbole, not statements of fact.

2. The Tripoli Letter

The Tripoli letter is not defamatory per se. (See supra pp. 3-4 for the complete text of Tripoli's letter). Skolnick claims Tripoli's letter defames him by falsely accusing him of questionable reporting tactics and publishing inaccurate facts. The court addresses each in turn.

a. Questionable Reporting Tactics:

Tripoli's assertion of questionable reporting tactics is similar to Yanucci's letter, in that it is based on Skolnick's identification of himself to CMS as

working for JAMA rather than the Post-Dispatch. The court's analysis of Yanucci's letter applies here as well, and need not be repeated. (See supra at pp. 15-17.) The underlying facts about Skolnick's identification of himself to CMS are true, and the remainder of Tripoli's comments on the subject are non-actionable opinion. (See id.) For the same reasons that Yanucci's letter was non-actionable opinion, Tripoli's assertion that Skolnick engaged in questionable reporting tactics is not actionable. (See id.)

Skolnick also argues that Tripoli's statement that Skolnick received information from plaintiffs lawyers seeking to advance their own agenda against CMS is defamatory per se because it impugns his integrity as a journalist. Under the innocent construction rule, the court should interpret the alleged defamation in context and give the words their natural and obvious implications and meanings. Bryson, 672 N.E.2d at 1215. A statement is not actionable per se when the court construes it in context and finds that it could reasonably interpret it as referring to someone other than the plaintiff. Id. Tripoli's statement that Skolnick may have been used by unnamed plaintiff's lawyers is reasonably capable of being construed as pertaining to the lawyers rather than Skolnick. Therefore, this portion of Tripoli's letter is not actionable.

b. Publication of Inaccurate Facts:

Skolnick claims that the Tripoli letter falsely states that Skolnick's reporting in the Post-Dispatch article was inaccurate. Defendants argue that these statements relate only to a particular setting, and are expressions of opinion. The court agrees on both points.

i. Particular Setting:

Illinois has done away with the rule that a statement limited to a single instance or particular selling is never actionable per se.Costello, 532 N.E.2d at 795-96. Instead, the court must examine the statement in context to determine whether the statement is truly limited to a single instance or generally impugns the plaintiffs fitness for his or her occupation. Id. Anderson, 667 N.E.2d at 1302-03. If the statement taken in context can be limited to single instance or particular setting, the court should so construe it. Anderson, 667 N.E.2d at 1302-03. In this case, Tripoli's letter plainly speaks of a particular setting, that is, Skolnick's investigation of CMS and subsequent reporting in the Post-Dispatch. The allegations that Skolnick engaged in questionable reporting tactics are limited to this setting, and there is nothing that generally impugns Skolnick's integrity as a journalist. Accordingly, Tripoli's "questionable reporting" statement is not actionable.

ii. Expression of Opinion:

Tripoli's letter is not actionable for another reason — it expresses his opinion. The court analyzes Tripoli's letter under both theOllman factors and the Hopewell test, which demonstrate that Tripoli's letter is opinion. The Ollman factors examine: "(1) the precision of the statement; (2) the verifiability of the statement; (3) literary context of the statement; and (4) public and social contexts of the statement."Moriarty, 732 N.E.2d at 740. Each of these factors indicates that Tripoli's letter expresses opinion. First, Tripoli's skepticism of the facts Skolnick reported in the Post-Dispatch articles is not precise. Indeed, there is not a single reference to any specific fact reported in the Post-Dispatch articles. Rather, Tripoli asserts generally that the Post-Dispatch articles contain inaccurate facts. As such, the firstOllman factor leans in favor of non-actionable opinion.

Second, Tripoli's assertion of inaccurate facts is not readily verifiable, which is a natural consequence of the lack of precision in Tripoli's letter. To verify Tripoli's statement would require litigation of all the facts reported in the Post-Dispatch articles. This exercise is better done in the marketplace of ideas than in a defamation action. Cf.Abrams, 250 U.S. at 630 (noting that an idea's acceptance in the market is the best test of

its truth, Holmes, J. dissenting); Dilworth, 75 F.3d at 309 (discussing the criticism and rough competition of the marketplace that comes with publication); Desnick v. American Broadcasting Co., 44 F.3d 1345, 1355 (7th Cir. 1995) (criticizing "tabloid-style" investigative journalism, but noting its importance in the marketplace).

Finally, the literary, public, and social contexts of Tripoli's letter demonstrate that it is a general response to public criticism rather than a dissemination of specific falsehoods about Skolnick. See Gardner, 731 N.E.2d at 355; cf. Dilworth, 75 F.3d at 309. Such a response is an opinion. In sum, all of the Ollman factors lean in favor of finding that Tripoli's letter expresses opinion, not facts.

The Hopewell test also establishes that Tripoli's letter is opinion rather than facts. The Hopewell test analyzes: (1) whether the language is precise and readily understood, bearing in mind that overly loose, figurative, rhetorical, or hyperbolic language negates the impression that the statement actually presents facts; (2) whether the general context of the statement negates the impression that the statement has factual content; and (3) whether the statement is susceptible of being objectively verified as true or false. Hopewell, 701 N.E.2d at 103-04. Again, the Tripoli letter's allegations of inaccuracies in the Post-Dispatch articles are loose and generalized, rather than specific. The context of the letter, a response to public criticism, refutes the idea that Tripoli is stating false defamatory facts about Skolnick. See id. at 105 (noting that statements made in a public dispute are likely to be perceived as substanceless rhetoric). And, as discussed above, it is difficult to objectively verify whether Tripoli's assertion of inaccurate reporting is true or false.

In sum, both the Ollman and Hopewell tests demonstrate that Tripoli's allegations of inaccurate reporting in the Post-Dispatch articles represent his opinion on the subject rather than defamatory facts about Skolnick.

3. The Miles Letter:

The Miles letter does not defame Skolnick. (See supra pg. 7 for the relevant portions of the Miles letter.) There are three allegedly defamatory statements in the Miles letter: (1) the letter takes issue with the Post-Dispatch articles' report of a particular inmate's death, and the report of an expert who opined that the death was the result of "criminal negligence;" (2) the letter disputes the Post-Dispatch articles' report that 12 million inmates return to society each year; and (3) the letter summarizes the Post-Dispatch articles as inaccurate and sensationalistic. Skolnick also alleges that the Miles letter contains a fourth statement (to the effect that the Post-Dispatch articles were based on biased sources that could not be independently verified), but fails to specifically cite to the portion of Miles letter that contains that allegation.[2] Because the Miles letter is lengthy, and Skolnick fails to give the court any direction, the court will not waste judicial resources scouring the record to find his evidence. See Doherty v. City of Chicago, 75 F.3d 318, 324 (7th Cir. 1996); Waldridge v. American Hoechst Corp., 24 F.3d 918, 922 (7th Cir. 1994). Thus, the court only considers the three allegations of defamation outlined in this opinion. Skolnick has waived any argument on the fourth allegation.

[2] Defendants cited the portions of Miles' letter that contain the first three allegedly defamatory statements. The court relied on Defendants' citation.

Defendants argue that the three statements in the Miles letter are not defamatory as a matter of law because the first two do not mention Skolnick by name, and the third is an expression of opinion. Skolnick, on the other hand, argues: (1) that the letter contains indirect references to him, which makes it defamatory in these circumstances; and (2) that the letter's reference to the "reporters" of the Post-Dispatch articles is sufficient because

Skolnick was one of the reporters. As explained below, the court finds nothing defamatory in the Miles letter.

Defamation allows recovery for harm to reputation. See Bryson, 672 N.E.2d at 1214; Hopewell, 701 N.E.2d at 102. The Miles letter simply presents another view of the facts reported in the Post-Dispatch articles, and comments on the general tenor of the articles. For example, the first allegedly defamatory statement states that one of the sources for the Post-Dispatch articles was an expert witness in litigation against CMS, and that his opinion was different from that of a coroner. The second allegedly defamatory statement takes issue with the Post-Dispatch report that 12 million inmates return to society each year by pointing out that there are only 1.7 million people incarcerated in the United States. These statements in no way harm Skolnick's reputation. Skolnick claims there is an inference that he failed to accurately report those facts, but that is too great a leap to support a claim for defamation per se. See Dubinsky, 708 N.E.2d at 447 (noting that defamation per se only exists if a statement is "so obviously and naturally harmful to the person to whom it refers that a showing of special damages is unnecessary and extrinsic facts are not needed to explain it."). Like the Tripoli letter, the first and second statements from the Miles letter are disputes of fact that are better sorted out in the marketplace than in a defamation action. Cf. Abrams, 250 U.S. at 630 (Holmes, J. dissenting); Dilworth, 75 F.3d at 309; Desnick, 44 F.3d at 1355.

The third allegation of defamation from Miles' letter is highly critical of the Post-Dispatch authors, but the statements are non-actionable opinion. Under both the Ollman and Hopewell tests, loose and rhetorical hyperbole is not actionable. See Hopewell, 701 N.E.2d at 103-04; cf. Moriarty v. Greene, 732 N.E.2d at 740. The final paragraph of Miles' letter uses such loose, rhetorical hyperbole. Miles' letter states that "the reporters' thesis is flawed, their statements are inaccurate, 1 and the tone is sensationalistic . . . [the] articles do a terrible disservice to [those] who care for inmate patients . . . [who are] . . . dedicated and hardworking people who do not deserve to be vilified by reporters who disregard the truth in pursuit of journalistic accolades. While these healthcare professionals have been unjustly maligned, the truth is the real victim." Imprecise statements such as this are not capable of verification, and cannot be construed as stating defamatory facts about Skolnick.

III. CONCLUSION

For the foregoing reasons, the court grants summary judgment in favor of Correctional Medical Services, Spectrum Healthcare Services, Richard Miles, and Louis Tripoli on Plaintiff's claims of defamation per se. The court denies Plaintiff's motion to strike as moot.

casetext

Maclean Health Employee List as of 10/03/2023

Angela Lucero
Anthony Campos
Briana Hawkins
Jessica Estrada
John Deterding
Kenneth Ley
Louis Roselli
Louis Tripoli
Preeya Sharma
Shawn DeFord
Sheri Hottle
Tram Harty
Victoria Curry
Zachary Isnec

Board of Pharmacy
2720 Gateway Oaks Dr, Suite 100
Sacramento CA 95833

000060

MACLEAN HEALTH
2233 WATT AVE STE 296
SACRAMENTO CA 95825

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618 WLS8057 03132023
www.pharmacy.ca.gov
Business, Consumer Services and Housing Agency
Department of Consumer Affairs Gavin Newsom, Governor

Pharmacy Hospital Pharmacy Clinic Exempt Hospital

Date: 3/13/2023 Inspector: Steven Kyle

INSPECTION REPORT

Wholesaler **X** Hypodermic

Firm: MACLEAN HEALTH Phone: (916) 284-0273 Address: 2233 WATT AVE STE 296 City: SACRAMENTO Zip: 95825

Ownership: CORPORATION

Permit #: WLS8057 Permit Exp: 3/1/2024 DEA#: DEA Exp: Date of Self Assessment Form: Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 7AM-7PM Hours Saturday: CLOSED Hours Sunday: CLOSED

EIC RPH Consultant Administrator

Staff RPH Name: License #: **License #: Staff Name:**

QUAN D NGUYEN RPH52916 **JOHN DETERDING** CORP OFFICER **ZACK ISNEC** TCH54469

Inspector Remarks:

Maclean Health is a licensed wholesaler in CA. Routine inspection requested for licensure in other states. The business is located on the second floor of an office building in its own suite. The suite includes several offices and a conference room.

The business model is to provide high cost non-controlled drugs to the Veterans Administration by having the drugs shipped from the manufacturer through a third party logistics provider. Maclean Health does not intend to have any drugs at its location.

Required:
All permits and licenses
Self-assessment
Listed owners and addresses
Designated representative in charge and notifications
Maintain a list of persons in charge of drug distribution, handling and storage, and duties
BOP email notification list

Facility
Clean, orderly, dry, well ventilated, free from rodents and insects, well lit, plumbing in good repair
Temperature & humidity monitoring
Quarantine area
Operate only when a designated representative or pharmacist is on the premises
Security: alarm to detect after-hours entry, outside perimeter well lit, computer security

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618 WLS8057 03132023
www.pharmacy.ca.gov

Drugs

Dangerous drugs secured, locked, and limited to authorized persons
Received and signed only by a designated representative or a pharmacist
Ordered only from licensed business, or licensed manufacturer
Repackaging case lots, no seals broken
Returns, only if originally purchased
Quarantine area

Sale or Transfer of Drugs
Only to business or persons licensed by BOP, prescriber board, manufacturer, or health care entity
From pharmacy if purchased, or to alleviate shortage
Out of state transactions
Common carriers used for shipping or delivery

Delivery of Drugs
To business address on license, signed by authorized person
Hospital deliveries to pharmacy or central receiving
Pharmacy delivery when pharmacy is closed

Policies and Procedures
Receipt of drugs
Security of drugs
Storage of drugs (including maintaining records to document proper storage)
Inventory of drugs (including correcting inaccuracies in inventories)
Distributing drugs
Identifying, recording and reporting theft or losses
Correcting errors and inaccuracies in inventories
Physical quarantine
Training, provided to all employees to assure all personnel comply with all licensing requirements

Record Keeping
Names, dates, and quantities
Pedigrees
Readily retrievable
Current inventory maintained
Offsite waiver
Electronic records produced by designated representative
Citations, fines, discipline for last 3 years
Preferential pricing records for LTC pharmacies, identify over 20 percent increases

Discussion
1. Self-assessment requirements and importance for compliance
2. Designated representative required on premises
3. Board of Pharmacy website resources

Provide the following by email within 7 days

1. Completed self-assessment with corrective plan of action for all items not in compliance

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
WLS8057 03132023
www.pharmacy.ca.gov

Steven Kyle, PharmD
Pharmacy Inspector
CA Board of Pharmacy

2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: 916-472-1036
Email: steven.kyle@dca.ca.gov

Ask An Inspector

Business, Consumer Services and Housing Agency Department of Consumer Affairs Gavin Newsom, Governor

The board can be contacted with questions pertaining to pharmacy law and regulations. • Email: ask.inspector@dca.ca.gov: Include name, organization, phone, and best call time • Fax: (916) 574-8618

• Phone: (916) 518-3100 (Monday through Thursday from 9 a.m. to 1 p.m.)

Educational topics:

- **The Script**: Available at www.pharmacy.ca.gov is The Script Newsletter.
- **Recently Approved Changes in Regulations:**
  - CCR 1746.4 – Pharmacist initiating and administering vaccines. Effective 1/25/2022.
  - CCR 1704 – Providing addresses (Email). Effective 4/1/2022.
  - CCR 1715.6 – Reporting drug loss. Effective 4/1/2022.
  - CCR 1717.5 – Automatic Refill Programs. Effective 7/1/2022.
  - CCR 1715 – Self-Assessment of a pharmacy by the PIC. Revised and adopted 1/2022 version is available online at www.pharmacy.ca.gov. Effective 10/1/2022.
  - CCR 1708.1 – Notification of temporary closure. Effective 10/1/2022.
  - CCR 1715.65 – Inventory Activities and Inventory Reconciliation Reports of Controlled Substances. Effective 1/1/2023.
- **Did you know:**
  - The Board created a Standard of Care Ad Hoc Committee to review, as directed by the Legislature in its sunset bill, whether movement to a standard of care enforcement model is both appropriate and feasible. The meetings can be viewed online by webcast and Webex on www.pharmacy.ca.gov. The next meetings are scheduled for 10/25/2022 and 2/1/2023. • These Board and Committee meetings are occurring virtually through WebEx and the Board welcomes comments. If you want to have your voices heard on these issues, please plan on attending one or more of these meetings.

Licensee Remarks:

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916)

574-8618 WLS8057 03132023
www.pharmacy.ca.gov
Business, Consumer Services and Housing Agency
Department of Consumer Affairs Gavin Newsom, Governor

I have reviewed, discussed,understand and received a copy of this form . (sign) _____

Exemptee

Exemptee (print) _____

Inspector (sign) _____ Owner(sign) _____ Steven Kyle

Inspector (print) _____ Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618 WLS8057 03132023
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 3/13/2023 Permit #: WLS8057 Time of Day: 7:57 AM

Name as shown on permit: **MACLEAN HEALTH**

Address: 2233 WATT AVE STE 296 City: SACRAMENTO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1784(b)(1)** Self-Assessment of a Wholesaler/Third-Party Logistics Provider by the Designated Representative-In-Charge or Responsible Manager.. In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever: A new license is issued.

   In that, no self assessment was completed by the DRIC within 30 days of the WLS license being issued on 03/18/2022.

2. **CCR 1781(a)** Pharmacist or Designated Representative on Premises and In Control.. A registered pharmacist, or a designated representative certified in accordance with Section 4053 of the Business and Professions Code, shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

   In that, there was no RPH or designated representative present and in control of the licensed premises.

I have reviewed, discussed, understand and received a copy of this form.

Signed

Inspector (sign)

Quan Nguyen

Inspector (print) Print Name

Title
Chief Pharmacist

Date

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 22.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Licensed Premises Name: Maclean Health

Address: 2233 Watt Ave, Ste 296, Sacramento, CA 95825

Phone: 800-683-4926 Licensed Premises Email address: info@macleanhealth.com

Ownership: Please mark one

☐ Sole Owner ☐ Partnership ☐ Corporation ☒ Limited Liability Company (LLC)

☐ Non-Licensed Owner ☐ Other (Please Specify) _____

CA License # WLS 8057 Expiration Date 03/01/2024

Other License #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory N/A

Hours: Weekdays 08:00 - 17:00 Sat_____ Sun_____ 24 Hours

DRIC / RM Quan Nguyen

DR License # / RPH License # RPH 52916 Expiration Date 01/31/2025

Website Address (optional): _____

Other Licensed Staff (DR, pharmacist (RPH)):

1. Quan Nguyen DR#/RPH# RPH52916 Exp. Date 01/31/2025
2. _____ DR#/RPH# _____ Exp. Date _____
3. _____ DR#/RPH# _____ Exp. Date _____
4. _____ DR#/RPH# _____ Exp. Date _____
5. _____ DR#/RPH# _____ Exp. Date _____
6. _____ DR#/RPH# _____ Exp. Date _____
7. _____ DR#/RPH# _____ Exp. Date _____
8. _____ DR#/RPH# _____ Exp. Date _____
9. _____ DR#/RPH# _____ Exp. Date _____
10. _____ DR#/RPH# _____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☒ ☐ ☐ 1.1. Review the current WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a],[c],[f]) **Attach a copy of the notification letter to the board to this document.**

☒ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (BPC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☒ ☐ ☐ 2.1.1. Are clean and orderly

☒ ☐ ☐ 2.1.2. Are well ventilated

☒ ☐ ☐ 2.1.3. Are free from rodents and insects

☒ ☐ ☐ 2.1.4. Are adequately lit

☒ ☐ ☐ 2.1.5. Have plumbing in good repair

☒ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see the standards set forth in the latest edition of the USP) (CCR 1780[b])

☒ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☒ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☒ ☐ ☐ 2.4. Is access to areas where dangerous drugs or dangerous devices are stored limited to authorized personnel? (BPC 4167, CCR 1780[c])

List personnel with keys to the area(s) where dangerous drugs or dangerous devices are stored (list by name or job title):

See Attached.

☒ ☐ ☐ 2.5. Does this business operate only when a DR or pharmacist is on the premises? (CCR 1781)

2.6. The licensed premises is equipped with the following specific security features:

☒ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☒ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☒ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

See Attached.

☐ ☒ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, or others, by receiving, inventorying and managing the disposition of outdated or nonsaleable dangerous drugs or devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN See Attached.

☐ ☐ ☒ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices (BPC 4163(c))

Date of approval from the board: N/A

Yes No N/A

☒ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: 03/23/2023

Email address registered with the board: pharmadmin@macleanhealth.com

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☒ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: 03/23/2023

Email address registered with the board: pharmadmin@macleanhealth.com

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☒ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☒ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☒ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☒ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

Yes No N/A

☒ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b], [c]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☒ ☐ ☐ 4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (BPC 4163[b], 4169)

☒ ☐ ☐ 4.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (BPC 4081, 4332)

☒ ☐ ☐ 4.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

☒ ☐ ☐ 5.1. When drugs are received by your business, are they delivered to the licensed premises, and received by and signed for only by a DR or a pharmacist? (BPC 4059.5[a])

☒ ☐ ☐ 5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN See attached.

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

6. Drug Stock

Yes No N/A

☒ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☒ ☐ ☐ 6.2. Are all drugs you order maintained in a secure manner at your licensed premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (BPC 4167)

☒ ☐ ☐ 6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (BPC 4342[a])

☒ ☐ ☐ 6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☒ ☐ ☐ 6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e])

☒ ☐ ☐ 6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e])

☒ ☐ ☐ 6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

7. Sale or Transfer of Drugs by this Business

Yes No N/A

☒ ☐ ☐ 7.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

7.2. Describe how you verify a business or person is appropriately licensed. (BPC 4059.5[a], [b],[d],[g], BPC 4169)

See Above

7.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

N/A

☒ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (BPC 4163[a]) Note: An authorized person can be a business or natural person.

7.5. Does your business only receive drugs from a pharmacy if:

☒ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☒ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☒ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

☒ ☐ ☐ 7.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☒ ☐ ☐ 7.6.1. transacted with a business licensed with this board as a WLS/3PL or pharmacy?

☒ ☐ ☐ 7.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☒ ☐ ☐ 7.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☒ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

N/A

7.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes	No	N/A	
☒	☐	☐	7.8.1. comply with all CA pharmacy laws related to the distribution of drugs?
☒	☐	☐	7.8.2. comply with the pharmacy law of the receiving state within the United States?
☒	☐	☐	7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?
☐	☐	☒	7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?
☐	☐	☒	7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (BPC 4059.5[e])

See attached.

☒	☐	☐	7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])
☒	☐	☐	7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)
☐	☒	☐	7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, B&PC 651, CCR 1766)
☐	☒	☐	7.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (BPC 650)

Yes No N/A

☐ ☒ ☐ 7.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (BPC 4066, CFR 1301.25)

CORRECTIVE ACTION OR ACTION PLAN See attached.

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)

Yes No N/A

☐☒☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

☒☐☐ 8.2. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☒ 8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150204[c])

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])
- ☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 8.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☒ 9.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☒ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (BPC 4166[a])

9.3. List the common carriers (shipping or delivery companies) you use.

See Attached.

CORRECTIVE ACTION OR ACTION PLAN See Attached.

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☒ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (BPC 4059.5[a])

☒ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (BPC 4059.5[d])

☒ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (BPC 4059.5[c])

☒ ☐ ☐ 10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN

11. Controlled Substances

Yes No N/A

☐ ☐ ☒ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☒ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☒ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (Specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☒ 11.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a], [c], [e])

☐ ☐ ☒ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☒ 11.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☒ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

N/A

☐ ☐ ☒ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☒ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☒ 11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (HSC 11153.5[a], [b], [c])

Yes No N/A

☐ ☐ ☒ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances. (CFR 1301.74[f])

☐ ☐ ☒ 11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

See attached.

☐ ☐ ☒ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☒ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☒ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☒ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☒ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☒ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☒ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

Yes No N/A

☐ ☐ ☒ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☒ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☒ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

☐ ☐ ☒ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☒ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☒ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74[g])

☐ ☐ ☒ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

☐ ☐ ☒ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☒ 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

☐ ☐ ☒ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN See attached.

12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes	No	N/A	
☒	☐	☐	12.1.1. Receipt of drugs
☒	☐	☐	12.1.2. Security of drugs
☒	☐	☐	12.1.3. Storage of drugs-(including maintaining records to document proper storage)
☒	☐	☐	12.1.4. Inventory of drug (including correcting inaccuracies in inventories)
☒	☐	☐	12.1.5. Distributing drugs
☒	☐	☐	12.1.6. Identifying, recording and reporting theft or losses
☒	☐	☐	12.1.7. Correcting errors and inaccuracies in inventories
			Physically quarantining and separating:
☒	☐	☐	12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs
☒	☐	☐	12.1.9. drugs that have been partially used
☒	☐	☐	12.1.10. drugs where the outer or secondary seals on the container have been broken
☒	☐	☐	12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug
☒	☐	☐	12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e],[f])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Training

Yes	No	N/A	
☐	☒	☐	13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN See attached.

_____

14. Dialysis Drugs

Yes No N/A

☐ ☒ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☒ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☒ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☒ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

☐ ☐ ☒ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN See attached.

15. Record Keeping Requirements

Yes No N/A

☒ ☐ ☐ 15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (BPC 4059[b])

☒ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☒ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081, 4105[c], 4332.

Yes No N/A

☒ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☒ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

☒ ☐ ☐ 15.6. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☒ ☐ ☐ 15.7. Are required records stored off-site only if a board issued written waiver has been granted?

15.8. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address N/A

☐ ☒ ☐ 15.9. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☒ ☐ ☐ 15.10. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☒ ☐ ☐ 15.11. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (BPC 4105[d][2])

☒ ☐ ☐ 15.12. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☒ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (BPC 4162[a][5]):

See attached.

☒ ☐ ☐ 15.14. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

Yes No N/A

☐ ☒ ☐ 15.15. Has this licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☒ 15.16. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN See attached.

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board

Yes No N/A

☒ ☐ ☐ 16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination. (BPC 4101[b], 4305.5[c]

☒ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager. (BPC 4305.5[a])

☐ ☐ ☒ 16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☒ 16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

☒ ☐ ☐ 16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☒ ☐ ☐ 16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

☒ ☐ ☐ 16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

Yes No N/A

☒ ☐ ☐ 16.8. The wholesaler maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ■ 16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities.
- ■ 16.8.2. identify purchases of any dangerous drugs at preferential or contract prices.
- ■ 16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☒ ☐ ☐ 16.9. I understand that this license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (BPC 4201[g])

☒ ☐ ☐ 16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☒ ☐ ☐ 16.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☒ ☐ ☐ 16.12. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

17. Additional Licenses/Permits Required

17.1. List all licenses and permits required to conduct this business, including local business licenses, licenses held in other states, permits or licenses required by foreign countries or other entities. (BPC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

See attached.

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) Quan Nguyen, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date 03/24/2023

Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

I, (please print) John Deterding, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the premises license issued by the California State Board of Pharmacy.

Signature John Deterding Date 3/24/2023

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov, at the California State Law Library, or at other libraries or Internet websites:

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulations (CCR), Title 16, Division 17 – California State Board of Pharmacy

Code of Federal Regulations (CFR), Title 21, Chapter 2 – Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law, Chapter 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

Response to 2.3, 2.4
No drugs are held or distributed at this time, but there is a separate locked, humidity and temperature controlled area for drugs if they were on site within the DR's office. Locks are installed on future DR's office door. Locking cabinet in the DR's office will hold any future drugs. Keys will only be held by DR or other licensed DRs on premises. Alarm system has been ordered to detect after hours entry.

Response to 2.5
DRIC is currently remote. On-site DR application to be submitted by 3/24/23.

Response to 2.6.1
Cameras are strategically positioned throughout Maclean Health, including the office entryway, interior hall, and DR's office. After hours entry is detected by Brivo, a cloud based security system. An alarm will sound and police will be called if an unauthorized after hours entry is detected.

Response to 2.6.2
The outside perimeter is well lit by street lights.

Response to 2.6.3
All computer records are stored on the cloud, with login credentials controlled by 2FA. Additional security includes Checkpoint Firewall Express Pro managed by AT&T, and SentinalOne endpoint security managed by AT&T.

Response to 2.7
The business is not a reverse distributor.

Response to 5.1
No drugs are received, stored, or distributed at this time. DR license application submitted the week of 3/24/23. Once approved, business will be compliant with section 5.1

Response to 7.5.2, 7.5.3
We are not a reverse distributor. No drugs are received from outside entities.

Response to 7.12
Maclean Health advertisements do not advertise dangerous drugs or devices.

Response to 7.13
No rebates, refunds, commissions or preferences, discounts, or other considerations are received for referring patients or customers.

Response to 7.14
Drugs and devices are not sold or furnished to the master or first officer of an ocean vessel.

Response to 9.1
Because we do not ever possess drugs, all pre-shipment inspections will be conducted by the manufacturer or manufacturers 3PL.

Response to section 14
No dialysis drugs are provided to patients.

Response to 15.9
All records are held on site at this time.

Response to 15.13
No citations, fines, or disciplinary action have been given within the last 3 years for the licensed premises, DR, or RM.

Response to 15.16
No dialysis drugs are dispensed from this premises.

Response to 16.3, 16.4
No controlled substances are ordered, on-hand, or shipped.

4L

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Progressive Medical, Inc.

Physical Address: 997 Horan Drive

City: Fenton State: MO Zip: 63026

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 314-961-5786 Website: progressivemedinc.com

Name of Designated Representative (DR): Roland (Dean) Sullivan

Licensing Company Email: cs@progressivemedinc.com DR Email: dsullivan@progressivemedinc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

R. Dean Sullivan

Original Signature (electronic, copies or stamps not accepted)

10-25-2023

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: West Pharma.Services IL., Ltd.
Address: 4 Hasheizaf St. City: Ra' anana State: Israel Zip: 4366411

Name: Marina Medical
Address: 8190 West State Road 84 City: Davie State: FL Zip: 33324

Name: Vesco Devices, Inc.
Address: 541 Lakewood Dr. City: Fairview State: TX Zip: 75069

Name: Inventex Medical, LLC.
Address: 7415 N. Melvina Avenue City: Niles State: IL Zip: 60714

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Missouri
Parent Company (if any):
Corporation/Organization Name: Progressive Medical, Inc.
Mailing Address: 997 Horan Drive
City: Fenton State: MO Zip: 63026
Telephone: 314-961-5786 Email: dsullivan@progressivemedinc.com
Contact Person Name: Dean Sullivan

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: Mark M. Martin
Business Name: Progressive Medical, Inc.
Business Address: 997 Horan Drive
City: Fenton State: MO Zip: 63026
Telephone: 314-961-5786 Email: mmartin@progressivemedinc.com

Section 8: NABP Accreditation/FDA Registration	**Yes**	**No**
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	**Publicly Traded**	**Non-publicly Traded**	**Partner-ship**	**Sole Owner**
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Progressive Medical, Inc.
Facility Name

Roland Dean Sullivan
Print Name of Authorized Person Submitting Application

R. Dean Sullivan
Original signature of Authorized Person (copies or stamps not accepted)

10-25-2023
Date

Board Use Only	Date Received: 11/8/23	Amount: $1000 -cc

Establishment:
PROGRESSIVE MEDICAL INC
997 Horan Dr
Fenton MO 63026
Registration Number: 3000236238
FEI Number*: 3000236238
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:
Progressive Medical Inc
997 Horan Drive
Fenton MO US 63026
Owner/Operator Number: 10028765

Official Correspondent:
Roland D Sullivan
997 Horan Drive
Fenton MO 63026
Phone: 314-9615786

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
PROGRESSIVE MEDICAL INC
997 Horan Dr
Fenton, MO 63026
Registration Number: 3000236238
FEI Number*: 3000236238
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2023

Owner/Operator:

Progressive Medical Inc[6]
997 Horan Drive
Fenton, MO US 63026
Owner/Operator Number: 10028765[7]

Official Correspondent:
Roland D Sullivan
997 Horan Drive
Fenton, MO 63026
Phone: 314-9615786

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10028765&OwnerOperat
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10028765&OwnerOperat

Page Last Updated: 10/09/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10028765&OwnerOperat

State of Missouri
Missouri Retail Sales License

LICENSEE:

PROGRESSIVE MEDICAL INC
997 HORAN DR
FENTON MO 63026
PROGRESSIVE MEDICAL INC

LICENSE ISSUED:

MARCH 28, 2013

MISSOURI TAX IDENTIFICATION NUMBER: 13599135

THE ISSUANCE OF THIS LICENSE IS CONTINGENT UPON THE LICENSEE'S COMPLIANCE IN ALL RESPECTS WITH THE REQUIREMENTS OF CHAPTER 144 RSMO, AND THE RULES PROMULGATED THEREUNDER.

THIS LICENSE IS VALID UNTIL CANCELLED AND SURRENDERED BY THE LICENSEE OR REVOKED BY THE DIRECTOR OF REVENUE.

THIS LICENSE MUST BE PROMINENTLY DISPLAYED IN THE PLACE OF BUSINESS.

DIRECTOR OF REVENUE

Brian K Long

THIS BUSINESS IS REGISTERED INSIDE THE CITY LIMITS OF FENTON IN THE COUNTY OF ST LOUIS AND YOU ARE LIABLE TO COLLECT AND REMIT ALL APPLICABLE STATE AND LOCAL SALES TAXES.

THIS LICENSE IS NOT ASSIGNABLE OR TRANSFERABLE

PROGRESSIVE MEDICAL

List of Officers 2023

1. Mark Martin- President & CEO
2. Greg Brewer- CFO
3. Shane Brendle- Controller / Compliance Officer

STATE OF MISSOURI

John R. Ashcroft
Secretary of State

CORPORATION DIVISION
CERTIFICATE OF GOOD STANDING

I, JOHN R. ASHCROFT, Secretary of State of the State of Missouri, do hereby certify that the records in my office and in my care and custody reveal that

PROGRESSIVE MEDICAL, INC.
00291169

was created under the laws of this State on the 14th day of July, 1986, and is in good standing, having fully complied with all requirements of this office.

IN TESTIMONY WHEREOF, I hereunto set my hand and cause to be affixed the GREAT SEAL of the State of Missouri. Done at the City of Jefferson, this 16th day of October, 2023.

Secretary of State

Certification Number: CERT-10162023-0113

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Licensed Drug Distributor

Wholesale Drug Distributor

VALID THROUGH OCTOBER 31, 2025
ORIGINAL CERTIFICATE/LICENSE NO. 2001007561
Roland Sullivan

PROGRESSIVE MEDICAL, INC.
PROGRESSIVE MEDICAL, INC
ROLAND D SULLIVAN, MIC
997 HORAN DRIVE
FENTON MO 63026
USA

EXECUTIVE DIRECTOR

Sheila Solon
DIVISION DIRECTOR

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/13/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
J.W. Terrill, a Marsh & McLennan Agency LLC co
825 Maryville Centre Drive
Suite 200
Chesterfield MO 63017

CONTACT NAME: Patti Monteith
PHONE (A/C, No, Ext): 314-594-2617 **FAX (A/C, No):** 888-307-1561
E-MAIL ADDRESS: patti.monteith@marshmma.com

INSURED PROGRMEDIC2
Progressive Medical, Inc.
997 Horan Drive
Fenton, MO 63026

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Phoenix Insurance Company	25623
INSURER B : Travelers Indemnity Company	25658
INSURER C : Travelers Indemnity Co of America	25666
INSURER D : Travelers Casualty and Surety Company	19038
INSURER E : Travelers Property Casualty Co of Amer	25674
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** 1510846963 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR			H6307N340183PHX23	7/15/2023	7/15/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 500,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ $
	GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER							
C	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY X HIRED AUTOS ONLY X SCHEDULED AUTOS NON-OWNED AUTOS ONLY			BA7N32177123I2G	7/15/2023	7/15/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
C	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 0			CUP7N343382312	7/15/2023	7/15/2024	EACH OCCURRENCE AGGREGATE $	$ 10,000,000 $ 10,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			UB7N3238072I2G	7/15/2023	7/15/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
D E	Crime Prod Liab-ClmsMade Excl from UMB			105965673 ZPP21P2956823I2	7/15/2023 7/15/2023	7/15/2024 7/15/2024	Ded - $5,000 OCC-$10,000 Ded Agg- $50,000 Ded	$1,000,000 10,000,000 OCC $10,000,000 AGG

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Policy#ZPL16N5793723I2 -07/15/23-07/15/24
Cyber Liability Coverage-Limit-$1,000,000 each wrongful act/$1,000,000 aggregate Ded-$25,000-Retro Date-01/01/19
Cyberfirst Technology Errors and Omissions Coverage-Claims Made-Retro Date-01/01/19-Limit-$1,000,000 each act/$1,000,000 aggregate Ded-$25,000
Evidence of WC coverage in New York

CERTIFICATE HOLDER

FOR INFORMATION ONLY
USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Ellen Patterson

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The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107906174

Application/License No. _____

Progressive Medical, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 997 Horan Drive, Fenton, MO 63026 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square, Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of October, 2023.

APPLICANT/PRINCIPAL
Progressive Medical, Inc.
COMPANY

Authorized Representative

SURETY

Travelers Casualty and Surety Company of America

Surety Company's Representative

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA HARTFORD, CONN.

Andrew P. Thome, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Dana A. Johnessee, Witness

Witness Andrea McCarthy, Witness

Countersigned by:

N/A
Nevada Resident Agent

State of **Missouri**
County of **St. Louis**

On **10/1/2023**, before me, a Notary Public in and for said County and State, residing therein, duly commissioned and sworn, personally appeared **Andrew P. Thome** known to me to be Attorney-in-Fact of

Travelers Casualty and Surety Company of America

the corporation described in and that executed the within and foregoing instrument, and known to me to be the person who executed the said instrument in behalf of said corporation, and he duly acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, the day and year stated in this certificate above.

Dana A Johnessee, Notary Public

My Commission Expires: _____

DANA A JOHNESSEE
NOTARY PUBLIC - NOTARY SEAL
STATE OF MISSOURI
COMMISSIONED FOR ST. LOUIS COUNTY
MY COMMISSION EXPIRES SEP. 20, 2025
ID #13516439

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint **ANDREW P THOME** of **CHESTERFIELD**, **Missouri**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **21st** day of **April**, **2021**.

State of Connecticut

City of Hartford ss.

By: _____
Robert L. Raney, Senior Vice President

On this the **21st** day of **April**, **2021**, before me personally appeared **Robert L. Raney**, who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June**, **2026**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this **1st** day of **October**, **2023**

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of MDEG Progressive Medical, Inc. MDEG License # (if applicable) N/A

Physical Address 997 Horan Dr.

City Fenton State MO Zip 63026

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-961-5786 Website progressivemedinc.com

Licensing Company Email N/A

Section 2: Personal Information

First Roland Middle Dean Last Sullivan

Alias(es, nicknames, name changes, etc.) Dean

Date of Birth [redacted] SSN or ITIN 2320 Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Fenton State MO Zip 63026

Telephone 314-961-5786 Email dsullivan@progressivemedinc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.320)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Phoenix			2000-2002	
Address		City	State	Zip
Online Degree Program		Phoenix	AZ	
Diploma/Degree obtained, if any				
Bachelors Degree in Business				
School Name			From - To (MM/YY – MM/YY)	
Meramec Community College			1990-1993	
Address		City	State	Zip
11333 Big Bend Road		Kirkwood	MO	63122
Diploma/Degree obtained, if any				
Associates Degree in Logistics				
School Name			From - To (MM/YY – MM/YY)	
Parks College of St. Louis University			1984	
Address		City	State	Zip
		St. Louis	MO	
Diploma/Degree obtained, if any				
High School Deploma				
School Name			From - To (MM/YY – MM/YY)	
Hazelwood High School				
Address		City	State	Zip
		St. Louis	MO	
Diploma/Degree obtained, if any				
High School				
School Name			From - To (MM/YY – MM/YY	
Riverview High School/middle school				
Address		City	State	Zip
		St. Louis	MO	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1984 - Present	[redacted]	Fenton	MO.	63026
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 2: An MDEG Administrator must provide proof that he/she has at least 5000 hours of verifiable work experience [illegible] by the applicant's employer(s) [illegible] Attach additional pages if necessary. Copies of W-2 forms [illegible]

Business Name	From - To (MM/YY – MM/YY)
Progressive Medical, Inc.	12/1995 to Present

Business Address	City	State	Zip
997 Horan Dr.	Fenton	MO.	63026

Phone	Title	Number of Employed Hours

Description of Duties

Manage Inventory, Purchasing, Logistics Managment, Compliance Team, MIC for Board Licenses

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title	Number of Employed Hours

Description of Duties

Continue on next page if additional space is needed.

Section 8 Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✓	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # 2+3. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
1977+1979	N/A	MO.	St. Louis	St. Louis
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		St. Louis County, MO.		
Reason/Charge				
Assault and resisting arrest				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
N/A			N/A	
Name of Business/Industry/Entity				

Provide explanation below:

Q2. The charges were made against me in 1977 and 1979, when I was 17 and 19 years old. Please accept my apology for my conduct as a teenager. I have no other criminal record since that time. I'm now 64 years old. I have a wonderful wife and two amazing daughters, and grandchildren. I'm a member of our local church and have accepted Jesus Christ into my heart. I've been employed with my present employer Progressive Medical, Inc. since 1995, going on 29 years.

Q3. Progressive Medical, Inc. still held our Missouri Board of Pharmacy license but was on probation from January 2009 to January 2010. Progressive Medical, Inc. had purchased products from a vendor that stated they had their license and was approved to supply products to us but found out later this was not the case. We stopped doing business with that vendor. This incident caused us problems but in the end we put polices in place to prevent this from happening again as we moved forward. I have included the offical notification letter of our completion of disciplinary action.

R. Dean Sullivan — 11-3-2023

Original Signature (electronic, copies or stamps not accepted) — Date

I, Roland Dean Sullivan, **certify that as the MDEG Administrator for** Progressive Medical, Inc., **that I (initial that you have read and meet the following requirements):**

1. RDS Have a high school diploma or its equivalent;
2. RDS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RDS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RDS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roland Dean Sullivan
Print Name (First, Last)

R. Dean Sullivan
Original Signature (electronic, copies or stamps not accepted)

11-3-2023
Date

Board Use Only	Date Received:

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

Pease See Settlement Agreement Included In Attachment C

February 1, 2010

Mark M Martin, President
Progressive Medical Inc.
11085 Gravois Industrial Court
Saint Louis, MO 63128

Dear Mr. Martin:

This is official notification that you have completed the terms of discipline for your facility at the above address with the Missouri Board of Pharmacy as of January 30, 2010. Feel free to contact this office if you have any questions or if we can be of assistance in the future.

Thank you for complying.

Sincerely,

Don Walker

DON WALKER
COMPLIANCE COORDINATOR

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1&6 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1977 &1979	N/A	MO	St. Louis	St. Louis
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		St. Louis, MO.		
Reason/Charge				
Assault and resisting arrest				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

Q1. The charges were made against me in 1977 and 1979, when I was 17 and 19 years old. Please accept my apology for my conduct as a teenager. I have no other criminal record since that time. I'm now 64 years old. I have a wonderful wife and two amazing daughters, and grandchildren. I'm a memeber of our local church and have accepted Jesus Christ into my heart. I worked for Gateway Apparel Ind. for over 17 years. I've been employed with my present employer Progressive Medical, Inc. since 1995. Going on 29 years.

Q6. Progressive Medical, Inc. still held our Missouri Boad of Pharmacy license but was on probation from January 2007 to Janurary of 2010. Progressive Medical had purchased products from a vendor that stated they had their license and was approved to supply products to us but found out later, this was not the case. We stopped doing business with that vendor. This incident caused us problems but in the end we put policies in place to prevent this from happening as we moved forward. I have included the offical notification letter of our completion of disciplinary action.

R. Dean Sullivan

Original Signature (electronic, copies or stamps not accepted)

10-25-2023

Date

I, Roland Dean Sullivan, **certify that as the designated representative for**

Progressive Medical, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RDS I am at least 21 years of age;
3. RDS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RDS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RDS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RDS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RDS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Roland Dean Sullivan

Print Name (First, Last)

R. Dean Sullivan

Original Signature (electronic, copies or stamps not accepted)

10-25-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roland Dean Sullivan

Print Name (First, Last)

R. Dean Sullivan

Original Signature (electronic, copies or stamps not accepted)

10-25-2023

Date

Please have this section completed in the presence of a Notary Public.

State of MISSOURI, ss. County of St. Louis

I, Dean Sullivan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

R. Dean Sullivan

Original Signature

10/25/2023

Date

Subscribed and Sworn to before me this 25 day of October

Diane M. Amsler

Notary Public Signature

DIANE M. AMSLER
Notary Public - Notary Seal
STATE OF MISSOURI
St. Louis County
My Commission Expires: April 16, 2025
Commission # 17223659

(Seal)

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
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800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

February 1, 2010

Mark M Martin, President
Progressive Medical Inc.
11085 Gravois Industrial Court
Saint Louis, MO 63128

Dear Mr. Martin:

This is official notification that you have completed the terms of discipline for your facility at the above address with the Missouri Board of Pharmacy as of January 30, 2010. Feel free to contact this office if you have any questions or if we can be of assistance in the future.

Thank you for complying.

Sincerely,

Don Walker

DON WALKER
COMPLIANCE COORDINATOR

Matt Blunt
Governor
State of Missouri

David T. Broeker, Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
W. Dale Finke, Director

BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625

www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Certified Article Number
7160 3901 9849 8239 0537
SENDERS RECORD

January 18, 2007

Mark M. Martin, President
Progressive Medical, Inc.
11085 Gravois Industrial Court
Saint Louis, MO 63128

Dear Mr. Martin:

Enclosed is a copy of the fully executed **Settlement Agreement Between State Board of Pharmacy and Progressive Medical, Inc.** regarding the discipline of your Missouri license to operate as a drug distributor.

The Agreement is scheduled to become effective January 31, 2007. You will receive additional communication from our office following that date. If you have any questions, please feel free to contact me at (573) 751-9056.

Sincerely,

DON WALKER
COMPLIANCE COORDINATOR

dw

Enclosure

cc: Roland D. Sullivan, MANAGER-IN-CHARGE
Robert Angstead, Attorney

Certified Article Number
7160 3901 9849 8239 0544
SENDERS RECORD

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND PROGRESSIVE MEDICAL, INC.

Come now Progressive Medical, Inc. ("Respondent" or "PMI") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license as a drug distributor will be subject to discipline.

Pursuant to the terms of §536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under §621.110, RSMo, and stipulate and agree that a final disposition of this matter shall be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorneys' fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit. For the purpose of

settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's license as a drug distributor, License Number DD2001007561, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo. The parties agree that this Settlement Agreement and any statements contained herein may not be used for or constitute an admission for any purposes other than to settle the disputes between the parties.

JOINT STIPULATION OF FACTS

1. The Missouri Board of Pharmacy (the "Board"), is an agency of the State of Missouri created and established by §338.110, RSMo, for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.

2. Progressive Medical, Inc., ("PMI") is located at 11085 Gravois Industrial Court, St. Louis, Missouri, and is licensed by the Board as a drug distributor under the laws of Missouri, License Number DD2001007561. PMI's license is, and was at all times relevant herein, current and active.

3. Beginning in 2003, PMI purchased pre-filled heparin syringes from Pinnacle Medical Supply, 3905 Melcer Drive, Suite 506, Rowlett, Texas ("Pinnacle") and distributed the syringes to certain of its customers.

4. On or about December 2, 2004, PMI received from the Board, via facsimile transmission, an Official Notification alerting PMI that Pinnacle, along with six (6) other distribution facilities, was not licensed in Missouri.

5. PMI understood the requirement that it only purchase and sell drugs and/or drug related devices from licensed or registered distributors.

6. In response to the Official Notification, PMI contacted Pinnacle and was advised by Pinnacle that Pinnacle was in the process of resolving all licensing issues with the State of Missouri. PMI did not contact the Board of Pharmacy or take other appropriate steps to confirm that Pinnacle was properly licensed in Missouri.

7. Thereafter, PMI continued to purchase pre-filled heparin syringes from Pinnacle.

8. In fact, Pinnacle is not, and has never been, licensed or registered by the Board to do business in the State of Missouri.

9. On January 24, 2005, PMI received a phone call from St. Louis University's health care system, SLUCare, referencing a problem with contamination of a pre-filled heparin syringe manufactured by Pinnacle and distributed by PMI. PMI claims that it immediately undertook to recall all pre-filled heparin syringes manufactured by Pinnacle and distributed by PMI. Under its recall procedure, PMI claims that it contacted by telephone, letter and fax, each customer to whom PMI had sold pre-filled heparin syringes manufactured by Pinnacle.

10. Thereafter, PMI ceased purchasing syringes or other drug-related devices from Pinnacle.

11. On or about August 3, 2005, the Board received a copy of a news article which was printed in the St. Louis Post Dispatch on August 3, 2005. The news article stated that St. Louis University's health care system, SLUCare, had filed suit, alleging that certain of its patients had become ill due to alleged contamination in syringes manufactured and distributed by Pinnacle and sold locally by PMI. It was noted in the news article that the Centers for Disease Control and Prevention linked Pinnacle's syringes to patients in St. Louis and in three other states who had become ill.

12. On or about January 18, 2006, Barbara Wood, an inspector for the Board, met with Roland Sullivan, the manager-in-charge of PMI.

13. At this meeting, Mr. Sullivan acknowledged to Ms. Wood that PMI had sold Pinnacle's pre-filled heparin syringes to hospitals and health care facilities, including SLUCare. The Board claims that Respondent had been previously warned by Inspector Wood regarding the requirement to only purchase drugs and/or drug related devices from licensed or registered distributors.

14. PMI's conduct of receiving and distributing drug related devices from an unlicensed distributor is in violation of 4 CSR 220-5.020 which states in pertinent part:

> (1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

15. PMI's conduct of distributing to hospitals drug related devices manufactured and sold by an unlicensed distributor is in violation of 4 CSR 220-5.030(1) which states:

> (1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.

16. The employees and customers of PMI have a relationship of professional trust and confidence in PMI in that employees and customers relied on PMI to make reasonable efforts to ensure compliance with all relevant drug distribution laws and standards of practice.

17. The Board believes that PMI's conduct alleged herein violates the professional trust and confidence of PMI's employees and customers.

18. PMI should not have solely relied on the representations of Pinnacle and should have taken appropriate steps to confirm that Pinnacle was properly licensed with the State of Missouri.

19. By solely relying on the representations of Pinnacle and not independently confirming that Pinnacle was properly licensed, PMI did not assure that all state laws concerning the distribution and control of drug-related devices were complied with so that no violations occurred.

20. PMI's conduct alleged herein constitutes a violation of the drug laws and regulations of this state.

JOINT CONCLUSIONS OF LAW

21. Cause exists for Petitioner to take disciplinary action against PMI's permit under §338.055, RSMo, which states in pertinent part:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

22. Cause exists for Petitioner to take disciplinary action against PMI's license under § 338.353.1, RSMo which states:

> 1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of a wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other state or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.3, RSMo:

1. Respondent's drug distributor license number DD2001007561 shall be placed on PROBATION for a period of three (3) years. The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

A. Respondent shall pay all required fees for licensing to the Board and shall

renew its license prior to October 31 for each licensing year.

B. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

C. If, after disciplinary sanctions have been imposed, Respondent fails to keep its Missouri license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

D. The parties to this Order/Agreement understand that the Board of Pharmacy will maintain this Order/Agreement as an open record of the Board as provided in Chapters 338, 610 and 620, RSMo.

E. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

2. Upon the expiration of said discipline, Respondent's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this

Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to §536.087, RSMo, or any claim arising under 42 U.S.C. §1983,

which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ REQUESTS

___MM___ DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO OPERATE AS A DRUG DISTRIBUTOR.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent=s license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement agreement goes into effect 15 days after the document is signed by the Board's representative.

RESPONDENT

PROGRESSIVE MEDICAL, INC.

By: _____
Mark M. Martin
President

Date: 11/27/06

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____

Date: 1-16-07

NEWMAN, COMLEY & RUTH P.C.

By: _____
Robert K. Angstead #37795
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: 573/634-2266
Fax: 573/636-3306

Attorneys for Petitioner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Progressive Medical, Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 997 Horan Drive

City Fenton State MO Zip 63026

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-961-5786 Website Progressivemedinc.com

Licensing Company Email _____

Section 2: Personal Information

First Roland Middle Dean Last Sullivan

Alias(es, nicknames, name changes, etc.) Dean

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 997 Horan Drive

City Fenton State MO Zip 63026

Telephone 314-961-5786 Email dsullivan@progressivemedinc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		2000-2002	
Address	**City**	**State**	**Zip**
On line degree program	Phoenix	AZ	
Diploma/Degree obtained, if any			
Bachelors Degree in Business			

School Name		From - To (MM/YY – MM/YY)	
Meramec Community College		1990-1993	
Address	**City**	**State**	**Zip**
11333 Big Bend Road	Kirkwood	MO	63122
Diploma/Degree obtained, if any			
Associates Degree in Logistics			

School Name		From - To (MM/YY – MM/YY)	
Parks College of St. Louis University		1980	
Address	**City**	**State**	**Zip**
	St. louis	Mo	
Diploma/Degree obtained, if any			
High School Deploma			

School Name		From - To (MM/YY – MM/YY)	
Hazelwood High School		1976-78	
Address	**City**	**State**	**Zip**
	St. louis	MO	
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY	
Riverview		1975	
Address	**City**	**State**	**Zip**
	St. Louis	MO	
Diploma/Degree obtained, if any			
High School			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1984 to Present	[redacted]	Fenton	MO	63026
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Progressive Medical, Inc.			12/1995 to Present
Business Address	**City**	**State**	**Zip**
997 Horan Drive	Fenton	MO	63026
Phone	**Title**	**Number of Employed Hours**	
314-961-5786	Materials Manager		
Description of Duties			
Manage Inventory, Purchasing, Logistics Managment, Compliance Team, MIC for Board Licences,			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Progressive Medical, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 13599135

Physical Address 997 Horan Dr.

City Fenton State MO Zip 63026

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 314-961-5786 Website progressivemedinc.com

Licensing Company Email _____

Section 2: Personal Information

First MARK Middle Malcom Last Martin

Alias(es, nicknames, name changes, etc.) NA

Date of Birth [redacted] SSN or ITIN NA Don't Give out! Sex ☒ M ☐ F ☐ X

Mailing Address MMartin@progressivemedinc.com

City Fenton State Mo Zip 63026

Telephone 314-961-5786 Email _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	**Yes**	**No**
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)
Lindenwood MBA	St. Charles Mo	St. Charles	Mo		12/85 – 12/86
Diploma/Degree obtained, if any					
School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)
St. Louis University MSN		St. Louis	Mo		5/83 – 12/84
Diploma/Degree obtained, if any					
School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)
St. Louis University BSN		St. Louis	Mo		1/80 – 1/82
Diploma/Degree obtained, if any					
School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)
Deaconess School of NS Dec					8/77 – 5/79
Diploma/Degree obtained, if any					
School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)
SFB		Wichita	Mo		8/72 – 5/75
Diploma/Degree obtained, if any					

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1988	[redacted]	Fenton	Mo	63026
From - To (MM/YY – MM/YY)			State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
PMI	6/86 – Now

Business Address	City	State	Zip
997 Horan Dr.	Fenton	MO	63026

Phone	Title
314-961-5786	Pres/CEO

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)
N/A	

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/20/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Martin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-25-2023

Date

Please have this section completed in the presence of a Notary Public.

State of MISSOURI, ss. County of ST. LOUIS

I, Mark Martin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10-25-2023

Date

Subscribed and Sworn to before me this 25th day of October.

Diane M. Amsler

Notary Public Signature

DIANE M. AMSLER
Notary Public - Notary Seal
STATE OF MISSOURI
St. Louis County
My Commission Expires: April 16, 2025
Commission # 17223659

(Seal)

2023

Office Employees

Amanda Pruyn
Amanda Vera
Cindy Mohrmann
Cole Walter
Dean Sullivan
Derrick Lacey
Diane Amsler
Don Walter
Greg Brewer
Greg Trimble
Jamie Todd
Linda Bagby
Mark Martin
Maureen Nichols
Melissa Pierce
Melissa Schellhamer
Michele Wayant
Mike Martin
Renee Richardson
Shane Brendle
Shane Martin
Susan Herbek
Tony Allen

Warehouse Employees

Bryan Manion
Chandler Clavin
Chris Morris
Ethan Wayant
Gary Stellern
Mike Conley
Pete Aschoff
Tyler Nanney

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03137	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: RVL Pharmaceuticals, Inc.

Physical Address: 400 Crossing Blvd, 6th Floor

City: Bridgewater State: NJ Zip: 08807

Mailing Address (if different from physical address): 400 Crossing Boulevard, 6th Floor

City: Bridgewater State: NJ Zip: 08807

Telephone: (908) 809-1300 Website: https://www.rvlpharma.com/

Name of Designated Representative (DR): Benjamin Markison

Licensing Company Email: statelicenses@rvlpharma.com DR Email: bmarkison@rvlpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Refresh Acquisitions Bidco LLC

Corporation/Organization Name: RVL Pharmaceuticals, Inc.

Mailing Address: 400 Crossing Boulevard, 6th Floor

City: Bridgewater State: NJ Zip: 08807

Telephone: (908) 809-1300 Email: statelicenses@rvlpharma.com

Contact Person Name: Brian Markison

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

RVL Pharmaceuticals, Inc.
Facility Name

James Schaub
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12/11/2023
Date

Board Use Only	Date Received: 12/18/23	Amount: $1000 - Check 1059

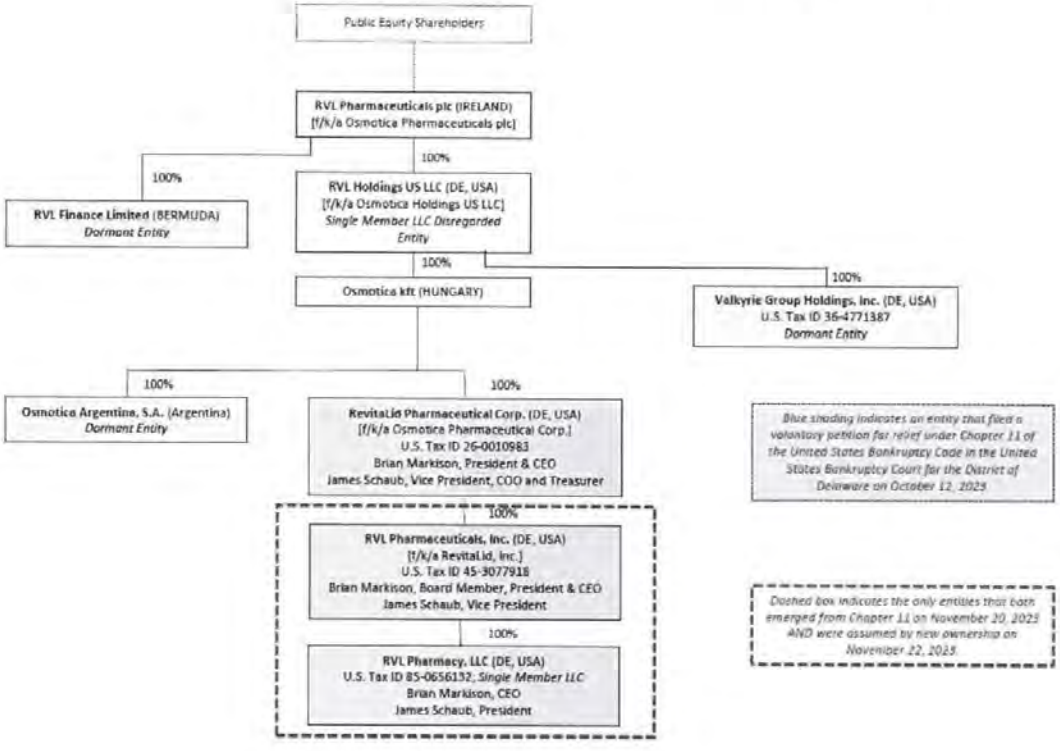
TwoLabs PHARMA SERVICES

RVL PHARMACEUTICALS, INC.

Exhibit A

Pre and Post Org Charts

RVL - Corporate Org. Chart
As of October 11, 2023
(PRE-PETITION)

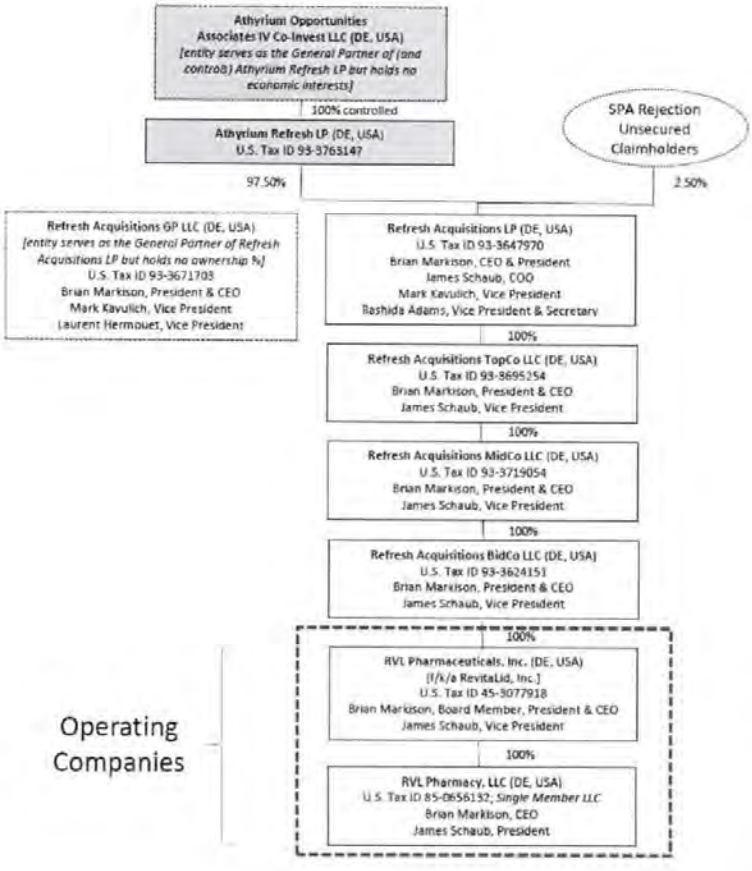


TwoLabs PHARMA SERVICES

RVL PHARMACEUTICALS, INC.

RVL - Corporate Org. Chart

As of November 23, 2023
(POST-PETITION)



Denotes an entity that is ultimately managed by Athyrium Capital Management, LP ("Athyrium") or controlled by an affiliate of Athyrium.

Affiliates of Athyrium, including the general partner of Athyrium Refresh LP (Athyrium Opportunities Associates IV Co-Invest LLC) beneficially owns 97.5% of the equity interests of RVL Pharmaceuticals, Inc., through their ownership of 97.5% of the equity of Refresh Acquisitions LP.

Dashed box indicates the only entities that both emerged from Chapter 11 on November 20, 2023 AND were assumed by new ownership on November 22, 2023

National Drug Code Directory

SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=NATIONAL DRUG CODE DIRECTORY&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

LINKEDIN (HTTPS://WWW.LINKEDIN.COM/SHAREARTICLE?MINI=TRUE&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&TITLE=NATIONAL DRUG CODE DIRECTORY&SOURCE=FDA)

PIN IT (HTTPS://WWW.PINTEREST.COM/PIN/CREATE/BUTTON/?URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM&DESCRIPTION=NATIONAL DRUG CODE DIRECTORY)

EMAIL (MAILTO:?SUBJECT=NATIONAL DRUG CODE DIRECTORY&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/NDC/DSP_SEARCHRESULT.CFM)

PRINT

Current through June 10, 2022

You have searched Finished drug products

Search Results: *'73687'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
UPNEEQ	73687-062-45	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	09/01/2020	N/A	NDA	45 AMPULE in 1 CARTON (73687-062-45) > .3 mL in 1 AMPULE (73687-062-70)
UPNEEQ	73687-062-25	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A	NDA	15 AMPULE in 1 CARTON (73687-062-25) > .3 mL in 1 AMPULE (73687-062-80)
UPNEEQ	73687-062-32	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A	NDA	30 AMPULE in 1 CARTON (73687-062-32) > .3 mL in 1 AMPULE (73687-062-70)
UPNEEQ	73687-062-34	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/21/2020	N/A	NDA	30 AMPULE in 1 CARTON (73687-062-34) > .3 mL in 1 AMPULE (73687-062-80)
UPNEEQ	73687-062-68	1 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	NDA212520	RVL Pharmaceuticals, Inc.	73687-062	Oxymetazoline hydrochloride ophthalmic	OXYMETAZOLINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	10/19/2020	N/A	NDA	5 AMPULE in 1 CARTON (73687-062-68) > .3 mL in 1 AMPULE (73687-062-80)

Showing 1 to 5 of 5 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

NV -Top 4 Suppliers- 2023

Prescriber Name	Account Name	Address	city	zipcode	state	npi	state_license_number
HARRY GREENBURG	Las Vegas Dermatology	653 N Town Center Dr Ste 414	LAS VEGAS	89144	NV	1447276175	11817
Andrea DEMPSEY	Dr. Andrea Dempsey, M.D.	7170 Smoke Ranch Rd Ste 150	LAS VEGAS	89128	NV	1497879035	12332
Julie Chang	Vegas Vision	4388 E CRAIG RD STE 150	LAS VEGAS	89115	NV	1417097171	401
VANESSA Kim	SPECTACLE EYECARE + EYEWEAR	9410 W SAHARA AVE STE 110	LAS VEGAS	89117	NV	1326220740	403

RVL
PHARMACEUTICALS, INC.

Description of Operations

RVL Pharmaceuticals, Inc. ("RVL") is a wholly-owned subsidiary of Refresh Acquisitions Bidco LLC, which is privately held. RVL's products are manufactured and packaged by a contract manufacturer and will be distributed by Eversana Life Science Services, who is licensed to ship pharmaceutical products into your state.

RVL Labeler Code: 73687
RVL product is distributed directly to licensed doctors and/or med-spas in your state.

Contract Manufacturer:
We are using the following contract manufacturer:

Nephron Pharmaceuticals Corporation
4500 12th Street Extension
West Columbia, SC 29172
FEIN: 3011158388

Nephron Pharmaceuticals Corporation manufactures RVL's product and packages finished product. At no time do they own the product, contract with RVL's customers, invoice, nor sell an RVL product. RVL's products are not Controlled Substances.

Third Party Logistics:
For distribution into commercial supply channels, Eversana acts as RVL's Third Party Logistics (3PL) provider to manage the storage and distribution of RVL's product to physicians throughout the United States.

Eversana Life Science Services, LLC
4580 Mendenhall Road
Memphis, TN 38141

RVL's hours of operation are 8:00 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday

RVL
PHARMACEUTICALS, INC.

Ownership Information

RVL Pharmaceuticals, Inc. is a privately held, wholly-owned subsidiary of Refresh Acquisitions Bidco LLC

Refresh Acquisitions Bidco LLC
400 Crossing Blvd.
Bridgewater, NJ 08807
Tax ID: 93-3624151

RVL Pharmaceuticals, Inc
Corporate Officers

Brian Markison, CEO
400 Crossing Blvd.
Bridgewater, NJ 08807

James Schaub, Vice
President 400 Crossing Blvd.
Bridgewater, NJ 08807

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "RVL PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5022283 8300

SR# 20234025597

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204637838

Date: 11-21-23

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0748097

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

400 CROSSING BLVD, 1ST FL BRIDGEWATER, NJ 08807-
400 CROSSING BLVD, 6TH FL BRIDGEWATER,NJ 08807-

Reg. No.
5005820

RVL PHARMACEUTICALS, INC.
400 CROSSING BLVD, 1ST FL
BRIDGEWATER, NJ 08807-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 12/12/2023

Registration Number: 5005820 **Registered as:** Wholesale

Name: RVL PHARMACEUTICALS, INC.

DBA:

Address: 400 CROSSING BLVD, 1ST FL, BRIDGEWATER, NJ 08807

Original Issue Date: 08/18/2020 **Expiration Date:** 01/31/2024

Current Issue Date: 11/07/2022

Disciplines: No

Additional Registered Addresses:
400 CROSSING BLVD, 6TH FL , BRIDGEWATER, NJ 08807

GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: Pharmaceutical Wholesalers Surety Bond

Bond No. : BLY1020177

Dated effective: 7/24/2020
(MONTH, DAY, YEAR)

executed by: RVL Pharmaceuticals, Inc. , **as Principal,**
(PRINCIPAL)

and by: The Hanover Insurance Company , **as Surety,**
(SURETY)

and in favor of : Nevada State Board of Pharmacy .
(OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	2500 Main Street Extension, Suite 6	400 Crossing Boulevard
Principal City	Sayreville	Bridgewater
Principal Zip	08871	08807

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 7/24/2021
(MONTH, DAY, YEAR)

Signed and Sealed 8/6/2021
(MONTH, DAY, YEAR)

RVL PHARMACEUTICALS, INC. CORPORATE SEAL EST 2011 DELAWARE

RVL Pharmaceuticals, Inc.
PRINCIPAL

BY: _____ General Counsel + Secretary
TITLE

The Hanover Insurance Company
SURETY

BY: _____
Wendy Lee Wadkins, ATTORNEY-IN-FACT

The Hanover Insurance Group

The Hanover Insurance Company, Bedford, New Hampshire
Assets and Liabilities as of December 31, 2020

ASSETS		2020
Cash in Banks (Including Short-Term Investments)		$ (57,030,013)
Bonds and Stocks		$6,691,401,588
Other Admitted Assets		$2,339,121,590
Total Admitted Assets		$8,973,493,165

LIABILITIES, CAPITAL AND SURPLUS

Reserve for Unearned Premiums		$1,893,941,039
Reserve for Loss and Loss Expense		$3,991,508,445
Reserve for Taxes		$ 10,515,546
Funds held under reinsurance treaties		$ 2,233,892
Reserve for all other liabilities		$ 492,418,556
Capital Stock - $1.00 par	$ 5,000,000	
Net Surplus	$2,577,875,687	
Policyholders' Surplus		$2,582,875,687
Total Liabilities, Capital and Surplus		$8,973,493,165

COMMONWEALTH OF MASSACHUSETTS

COUNTY OF WORCESTER

I, Jeffrey Farber, Assistant Treasurer of The Hanover Insurance Company, being duly sworn deposes and says that he is the above described officer of said Company, and certifies that the forgoing statement is a true statement of the condition and affairs of the said Company on December 31, 2020.

J. Farber

Jeffrey Farber
Assistant Treasurer

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Wendy Lee Wadkins, Christopher F. Mulvaney, Charles N. Parsons, Vincent J. Mancini and/or Pablo Rios, Jr.

Of **Willis of Pennsylvania, Inc. of Radnor, PA** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Twenty Five Million and No/100 ($25,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this **14th** day of **February, 2018**.

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this **14th** day of **February, 2018** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 6thday of August 2021

CERTIFIED COPY

Theodore G. Martinez, Vice President

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. BLY2020177

Application/License No. _____

RVL Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2500 Main Street Extension, Suite 6, Sayreville, New Jersey 08871 (Address of Applicant/Principal), as PRINCIPAL, and The Hanover Insurance Company (Surety Company), a corporation organized under the laws of the state of New Hampshire (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 440 Lincoln Street, Worcester, Massachusetts 01653-0002 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 24, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 24th day of July, 20 20.

APPLICANT/PRINCIPAL
RVL PHARMACEUTICALS, INC.

Authorized Representative

SURETY COMPANY
THE HANOVER INSURANCE COMPANY

Surety Company's Representative

Wendy Lee Wadkins, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Pablo Rios, Jr.

Witness Danielle M. Bechard

Countersigned by:

Non- Nevada Resident Agent License #3091632
Wendy Lee Wadkins

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Wendy Lee Wadkins, Christopher F. Mulvaney, Charles N. Parsons, Vincent J. Mancini and/or Pablo Rios, Jr.

Of **Willis of Pennsylvania, Inc. of Radnor, PA** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Twenty Five Million and No/100 ($25,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this **14th** day of **February, 2018**.

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this **14th** day of **February, 2018** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 24thday of July 2020

CERTIFIED COPY

Theodore G. Martinez, Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RVL Pharmaceuticals, Inc.

Pharmacy/Wholesaler License # (if applicable) WH03137

Physical Address 400 Crossing Blvd, 6th Floor

City Bridgewater State NJ Zip 08807

Mailing Address (if different from physical address) 400 Crossing Boulevard, 6th Floor

City Bridgewater State NJ Zip 08807

Telephone (908) 809-1300 Website https://www.rvlpharma.com/

Licensing Company Email statelicenses@rvlpharma.com

Section 2: Personal Information

First Benjamin Middle _____ Last Markison

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 400 Crossing Blvd., 6th Floor

City Bridgewater State NJ Zip 08807

Telephone (908) 809-1300 Email bmarkison@rvlpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Miami		Completed 2014	
Address	**City**	**State**	**Zip**
1320 S Dixie Hwy	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelor's degree			

School Name		From - To (MM/YY – MM/YY)	
The Pennington School		2006-2010	
Address	**City**	**State**	**Zip**
112 W Delaware Ave	Pennington	NJ	08534
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/01/2020 - present	[redacted]	Mantoloking	NJ	08738
01/11-2020		Princeton	NJ	08540
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
RVL Pharmaceuticals, Inc.			2021-Present
Business Address	**City**	**State**	**Zip**
400 Crossing Blvd, 6th Floor	Bridgewater	NJ	08807
Phone	**Title**	**Number of Employed Hours**	
(908) 809-1300	Director, Supply Chain & Customer Service	4,000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Trigen Laboratories, LLC			2015-2021
Business Address	**City**	**State**	**Zip**
2500 Main Street Extension Ste 6	Sayreville	NJ	08872
Phone	**Title**	**Number of Employed Hours**	
(908) 809-1300	Senior Manager, Warehouse Operations & RVL Supply Chain	10,000	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	x	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
			See attached	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/11/2023
Date

I, Benjamin Markison, **certify that as the designated representative for**

RVL Pharmaceuticals, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BM I am at least 21 years of age;
3. BM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Benjamin Markison
Print Name (First, Last)

Ben Markison
Original Signature (electronic, copies or stamps not accepted)

12/11/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Markison

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/11/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Somerset

I, Benjamin Markison, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/11/23

Date

Subscribed and Sworn to before me this 11th day of December 2023

Notary Public Signature

Alessio V. Brasile

ALESSIO V BRASILE
Notary Public, State of New Jersey
My Commission Expires Dec 12, 2026

(Seal)

Benjamin J. Markison
[redacted]

Education

University of Miami, December 2014
Coral Gables, FL
Major: Communications
Minor: Sports Administration

Experience:

Osmotica Pharmaceuticals
RVL Pharmaceuticals, INC.

Sr. Manager, RVL Supply Chain Operations (June 2021 – Present)

- Manage production and inventory based upon input from commercial team
- Coordinate and communicate forecast requirement updates to Suppliers and Contract Manufacturing Organizations (CMOs)
- Work closely with Internal/External Manufacturing organizations to ensure that the production plans are achievable using capacity planning, level loading, materials availability planning, etc.
- Manage inventory levels to ensure order fulfillment
- Responsible for monitoring CMO's inventories to ensure commercial production and clinical supply production are not interrupted due to material or component shortages or expiry dating
- Responsible for analyzing monthly inventory levels for finished goods, semi-finished goods and API, to ensure adherence to safety stock requirements
- Manage product output as supplied to third party logistics (3PL) distribution
- Monitoring of Bill of Materials and Component Specifications at CMO's and Suppliers
- Manage product serialization activities as required
- Developed policies and procedures to run an efficient and complaint department
- Manage inventory through establishment of control of inventory, regular cycle counts, and year-end physical counts for accuracy.
- Maintain inventory control of finished product and samples to include proper storage, stock rotation, replenishment, cycle counting, availability, release status, and related activities.
- Interface with appropriate personnel to oversee the effective implementation and maintenance of logistics systems, such as Microsoft Dynamics AX, Serialization, Small Parcel Integrated Shipping Solutions, etc. as they relate to the operations of the DC
- Work with internal departments to ensure operations are compliant with all applicable government agencies, including, but not limited to, FDA, OSHA, State of New Jersey, etc.
- Designated representative on all State distribution licenses
- Lead delegate from Distribution Operations during third-party as well as internal audits or inspections.
- Manage all aspects of traffic activities for inbound and outbound freight to optimize service and cost, including negotiating rates and arrangements, scheduling individual shipments, selecting the most effective mode of transportation, monitoring service and working with carriers on improvements, negotiating settlement of damage claims, and communicating RVL's approved/preferred carrier information to internal departments, vendors, and customers.

Supply Chain Analyst, Marietta, GA, and Sayreville NJ (July 2016- June 2017)

- Process backorder reports & provide to customers weekly
- Manage backorder status & coordinate shipment/order processing once released
- Develop internal backorder report and distribute weekly.
- Issue & maintain all Trigen & Vertical Return Goods Authorizations including Return Authorizations for destruction shipments and complaints
- Respond to customer inquiries as it relates to returns, credits, overages/shortages, inventory research for Trigen & Vertical
- Perform customer service functions, support sales & customer inquiries, PO research & provide tracking information
- Responsible for Returns & Customer Service/Sales support
- Support Warehouse Manager:
- Develop and track distribution metrics.

Pharmaceutical Sales Representative, Monmouth County, NJ (February 2015- July 2016)

- Accomplished 100% Quota Attainment
- Generated prescriptions through developing and maintaining relationships with doctors and offices within territory

Marketing/Sales Internship, Sayreville, NJ (May 2014 – August 2014)

- Assisted Marketing department in developing detail aids
- Reviewed weekly reports for accuracy for the field sales force
- Supported inside sales representatives with data entry
- Strategically organized warehouse for more efficient pick, pack, and shipping
- Contributed to construction professional sales representative sample kits

Comcast Spectacor - Marketing Internship, Philadelphia, PA (May 2013-August 2013)

- Contributed to client and sales development for professional lacrosse team
- Created content and developed administrative pages for WingsLAX.com
- Assisted in the execution of marketing programs and events
- Brainstormed new marketing and game entertainment ideas
- Contributed to client and sales development

The Rehabilitation Center – Physical Therapy Associate, Princeton, NJ (June 2012 – August 2012)

- Reported to the Head of Physical Therapy
- Assisted with prepping patients for physical and exercise therapy
- Provided administrative support, including scheduling and outpatient instruction follow-up

True North Lacrosse - Sales and Website Design, Pennington, NJ (September 2010 –August 2011)

- Scheduled camps and activities for players
- Ran clinics specializing in team defense and proper player alignment
- Overlooked the store part-time
- Managed sales, inventory and scheduling

References available upon request.

Vertical Pharmaceuticals, LLC
Trigen Laboratories, LLC

Manager of Warehouse Operations, Sayreville NJ (June 2017 – June 2021)

- Lead and direct the work of Warehouse Associates
- Act as designated representative for all Federal and State licenses
- Manage the Distribution staff in the processes of order fulfillment to include product receipt, picking, confirmation, checking, packing and shipment.
- Monitor floor operations and adjust assignments as appropriate to meet deadlines and overall corporate objectives
- Maintain inventory control of finished product and samples to include proper storage, stock rotation, replenishment, cycle counting, availability, release status, and related activities
- Maintain a safe working environment through education, training and continuous improvement of material handling functions
- Maintain a fully trained staff through identification, pursuit, and implementation of training programs to assure compliance with GMPs, DEA and OSHA regulations, and corporate requirements
- Interface with internal departments to ensure the facility and operations are compliant with all applicable government agencies, including, but not limited to, FDA, DEA, OSHA, State of New Jersey, etc.
- Lead delegate from Distribution Operations during third-party as well as internal audits or inspections.
- Author SOPs when required and execute training for all affected Distribution staff.
- Manage all aspects of traffic activities for inbound and outbound freight to optimize service and cost, including negotiating rates and arrangements, scheduling individual shipments, selecting the most effective mode of transportation, monitoring service and working with carriers on improvements, negotiating settlement of damage claims, and communicating Vertical's approved/preferred carrier information to internal departments, vendors, and customers.
- Harmonized multiple standard operating procedures (SOPs), between two companies
- Successfully implemented ERP system, Microsoft Dynamics AX 2012. Worked with individuals from IT, and third party integration Company (RSM), to ensure the system was running at a functional level.

RVL
PHARMACEUTICALS, INC.

Names

Barnes, Nancy
Bonante, Jo Ann
Chester, Claude
Confalone, Deana
Daly, Gregory
Desilva, Paul
Doyle, Thomas
Ducey-Munde, Joan
Fee, Nicholas
Galvin, Paul
Gembarski, Katerina
Giordano, Kathleen
Green, James Aaron
Haig, Brian
Kee, Nickee
Klein, Christopher
Malieckal, Sanjay
Markison, Benjamin
Markison, Brian A.
Miller, Jarret
Owens, Eifwa Pollyann
Rivera, Javier
Schaub, James
Stavole, Joann
Supetran, Myralyn
Tamke, Connor
Thieme, Brittany
Tinescu, Ada
Weissman, Craig
Wozniak, Teresa

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
REVITALID PHARMACEUTICAL CORP., *et al.*,	)	Case No. 23-11704 (BLS)
Debtors.[1]	)	(Jointly Administered)
	)	**Re: Docket Nos. 16, 90 & 126**

NOTICE OF (I) OCCURRENCE OF EFFECTIVE DATE AND (II) ENTRY OF ORDER APPROVING (A) THE DISCLOSURE STATEMENT AND (B) CONFIRMING THE AMENDED JOINT PREPACKAGED CHAPTER 11 PLAN OF REVITALID PHARMACEUTICAL CORP. AND ITS SUBSIDIARIES

TO ALL CREDITORS, INTEREST HOLDERS, AND OTHER PARTIES IN INTEREST:

PLEASE TAKE NOTICE that on November 20, 2023, the United States Bankruptcy Court for the District of Delaware (the "**Bankruptcy Court**") entered an order [Docket No. 126] (the "**Confirmation Order**") confirming the *Amended Joint Prepackaged Chapter 11 Plan of RevitaLid Pharmaceutical Corp. and Its Subsidiaries* [Docket No. 90] (as may be amended, modified, or supplemented, the "**Plan**")[2] (attached as **Exhibit A** to the Confirmation Order) and approving the *Disclosure Statement for the Joint Prepackaged Chapter 11 Plan of RevitaLid Pharmaceutical Corp. and Its Subsidiaries* [Docket No. 16] of RevitaLid Pharmaceutical Corp. and certain of its affiliates that are debtors and debtors in possession (collectively, the "**Debtors**") in the above-captioned chapter 11 cases (the "**Chapter 11 Cases**").

PLEASE TAKE FURTHER NOTICE that the Effective Date occurred on November 22, 2023.

PLEASE TAKE FURTHER NOTICE that the Confirmation Order, the Plan and the Disclosure Statement may be obtained free of charge by visiting the Debtors' chapter 11 restructuring website maintained by the Debtors' voting agent, Kroll Restructuring Administration LLC (the "**Voting Agent**"), at: https://restructuring.ra.kroll.com/RVL. Copies of the Confirmation Order, the Plan and Disclosure Statement may also be obtained by calling the Voting Agent at (844) 870-7074 (U.S./Canada, toll-free) or +1 (646) 651-1184 (international, toll) or by sending an electronic mail message to RVLInfo@ra.kroll.com (with "RevitaLid Solicitation" in the subject line).

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[1] The Debtors in these chapter 11 cases, along with the last four digits of each Debtor's federal tax identification number, are: RevitaLid Pharmaceutical Corp. (0983), RVL Pharmaceuticals, Inc. (7918), and RVL Pharmacy, LLC (6132). The location of the Debtors' principal place of business is 400 Crossing Boulevard, Bridgewater, New Jersey 08807.

[2] Capitalized terms not otherwise defined herein have the meanings ascribed to them in the Plan and the Confirmation Order, as applicable.

PLEASE TAKE FURTHER NOTICE that the Bankruptcy Court has approved certain discharge, release, exculpation, injunction, and related provisions in Article VIII of the Plan.

PLEASE TAKE FURTHER NOTICE that the terms of the Plan and the Plan Supplement shall be immediately effective and enforceable and deemed binding upon the Debtors, the Reorganized Debtors, and any and all holders of Claims or Interests (irrespective of whether such Claims or Interests are deemed to have accepted the Plan), all Entities that are parties to or are subject to the settlements, compromises, releases, discharges, and injunctions described in the Plan, each Entity acquiring property under the Plan, and any and all non-Debtor parties to Executory Contracts and Unexpired Leases with the Debtors.

PLEASE TAKE FURTHER NOTICE that each Executory Contract and Unexpired Lease that has otherwise not been rejected (as set forth in the Rejected Contracts and Leases Schedule) shall be deemed assumed by the applicable Debtor, without the need for any further notice to or action, order, or approval of the Bankruptcy Court, as of the Effective Date under section 365 of the Bankruptcy Code. In the event that the rejection of an Executory Contract or Unexpired Lease under the Plan results in damages to the other party or parties to such contract or lease, any Claim for such damages shall be forever barred and shall not be enforceable against the applicable Debtor or RVL Corp. or the Reorganized Debtor, as applicable, or their respective Estate, properties or interests in property, unless a Proof of Claim is filed with the Bankruptcy Court and served upon the applicable Debtor no later than thirty (30) days after the later of (i) November 20, 2023 or (ii) the effective date of the rejection of such Executory Contract or Unexpired Lease, as set forth on the Rejected Contracts and Leases Schedule or order of the Bankruptcy Court. For the avoidance of doubt, the Confirmation Order constitutes the Bankruptcy Court's approval of the rejection of all the leases and contracts identified in the Rejected Contracts and Leases Schedule.

PLEASE TAKE FURTHER NOTICE that **December 22, 2023** is the deadline for filing requests for payment of Administrative Expense Claims (other than Professional Fee Claims).

PLEASE TAKE FURTHER NOTICE that **January 8, 2024** is the deadline for all Professionals or other Entities requesting compensation or reimbursement of expenses pursuant to sections 327, 328, 330, 331, 503(b), or section 1103 of the Bankruptcy Code for services rendered before the Effective Date (including any compensation requested by any Professional or any other Entity for making a substantial contribution in the Chapter 11 Cases) to file and serve final requests for payment of Professional Fee Claims.

PLEASE TAKE FURTHER NOTICE that the Plan and the Confirmation Order contain other provisions that may affect your rights. You are encouraged to review the Plan and the Confirmation Order in their entirety.

Dated: November 22, 2023
Wilmington, Delaware

/s/ Brendan J. Schlauch

Mark D. Collins (No. 2981)
Brendan J. Schlauch (No. 6115)
Matthew P. Milana (No. 6681)
Huiqi Liu (No. 6850)
Alexander R. Steiger (No. 7139)
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
Telephone: 302-651-7700
Fax: 302-651-7701
Email: collins@rlf.com
schlauch@rlf.com
milana@rlf.com
liu@rlf.com
steiger@rlf.com

-and-

Gregg M. Galardi (No. 2991)
Cristine Pirro Schwarzman (Admitted *Pro Hac Vice*)
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036
Telephone: 212-596-9000
Fax: 212-596-9090
Email: gregg.galardi@ropesgray.com
cristine.schwarzman@ropesgray.com

Counsel to the Debtors

RVL License list

Licensing State	License Type	License #	Issue Date	Expiration Date
Alabama	Private Label Distributor - Virtual Manufacturer	196201	3/15/2022	12/31/2024
Alaska	Non-Resident Wholesale Distributor	196402	6/9/2022	6/30/2024
Arizona	Manufacturer	M001928	3/16/2022	10/31/2025
Arkansas	Wholesale Distributor	WD05420	8/31/2020	12/31/2024
Connecticut	OOS Manufacturer	CSM.0001849-OOS	8/31/2020	1/1/2050
Florida	Complimentary Drug Dist	40923	7/15/2022	7/31/2024
Florida	Virtual Manufacturer	46335	7/15/2022	7/31/2024
Georgia	Wholesaler Pharmacy	PHWH005423	10/4/2022	6/30/2025
Idaho	Virtual Manufacturer	M67289	7/19/2022	12/31/2023
Iowa	Limited Distributor	41517	1/25/2022	12/31/2023
Kansas	Manufacturer	4-118042	6/14/2022	6/30/2024
Louisiana	Wholesaler	10494	1/25/2022	12/31/2024
Maryland	Distributor	D07060	2/9/2022	5/31/2025
Michigan	Wholesaler	5306007147	10/26/2022	10/26/2024
Minnesota	Manufacturer	462159	7/13/2022	5/31/2024
Mississippi	Drug Facility Permit	18431	1/21/2022	12/31/2023
Montana	Wholesale Distributor	PHA-WDD-LIC-83699	2/17/2022	11/30/2024
Nevada	Wholesale Distributor	WH03137	3/4/2022	10/31/2024
New Hampshire	Manufacturer/Wholesaler/Distributor	07401	3/4/2022	6/30/2024
New Jersey	Wholesale	5005820	8/18/2020	1/31/2024
New Mexico	Wholesale Distributor	WD00013071	1/20/2022	12/31/2025
New York	Non Resident WLS	039313	12/6/2021	11/30/2024
North Carolina	Virtual Manufacturer	1756	1/13/2022	12/31/2023
North Dakota	Virtual Manufacturer	Whol2759	1/12/2022	6/30/2024
Ohio	Wholesale Category II	0130000448	3/3/2022	6/30/2025
Oklahoma	Manufacturer	88-M-7467	6/2/2022	6/30/2024
Oregon	Manufacturer	M-0003652	11/18/2021	9/30/2024
Pennsylvania	Manufacturer	1000004256	1/10/2022	1/31/2024
South Dakota	Wholesale Distributor	600-3385	1/19/2022	12/31/2023
Tennessee	Manufacturer	00007238	10/11/2021	5/31/2024
Texas	OOS Wholesaler	1003343	2/24/2022	11/29/2025
Utah	Pharmacy Class C	12867896-1710	6/1/2022	9/30/2025
Vermont	Wholesale Drug Outlet	163.0000617	5/23/2022	7/31/2025
Washington	Wholesaler	PHWH.FX.61322254		9/30/2024
Washington D.C.	Non-resident Manufacturer	DM2200127	7/11/2022	7/31/2024
West Virginia	Manufacturer	MR0552279	10/1/2021	6/30/2024

4N

SGN-823-NV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02809	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Seagen Inc.

Physical Address: 21823 30th Drive SE

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.seagen.com

Name of Designated Representative (DR): Susan Lynn Fletcher

Licensing Company Email: SGN@slsny.com DR Email: sfletcher@seagen.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled * (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: US Government		☒ Others: Manufacturer - Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2023	N/A	CA	Sacramento	Sacramento County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2022 99946	California State Board of Pharmacy

Reason/Charge
Letter of Admonishment

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Pfizer Inc

Provide explanation below:

Grandparent Company, Pfizer Inc. received a Letter of Admonition from the CA Board of Pharmacy for failing to notify the board of a new Designated Representative within the required 30 days. Please see the attached Letter of Admonishment and response from client.

Susan E Grant

Original Signature (electronic, copies or stamps not accepted)

12/14/2023

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/14/2011	N/A	CO	Denver	Denver County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
#2011-0838, #2011-1101, #2011-0835, #2011-1136, #2011-0833	Colorado State Board of Pharmacy

Reason/Charge
Failure to report a Change of DR within Colorado's filing deadline

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Pfizer Inc

Provide explanation below:

Please be advised that during September/October of 2010, Grandparent Company, Pfizer Inc received complaints from the Colorado Department of Regulatory Agencies (DORA) related to the timeliness in reporting a change to the designated representative at 5 of the Pfizer distribution site locations. Pfizer has provided DORA with all of the required designated representative change information and has settled all of the complaints. The matter is now resolved and all of the licenses involved are currently in good standing.

S E D Susan E Grant

Original Signature (electronic, copies or stamps not accepted)

12/17/2013

Date

CA grandparent discipline

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 23, 2023

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

PFIZER INC
ATTN: ALBERT BOURLA, CEO
1855 SHELBY OAKS DR N
MEMPHIS, TN 38134

RE: CI 2022 99946
PFIZER INC
OSD 4069

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 4161(j) - A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge

Failure to Notify within 30 Days – Business and Professions Code section 4161(j) requires a nonresident wholesaler or nonresident third-party logistics provider to identify and notify the Board of a new designated representative-in-charge (DRIC) or responsible manager (RMG) within 30 days of the date that the prior DRIC or RMG ceases to be the DRIC or RMG. Specifically, on March 3, 2022 the Board received an Application for Change of Designated Representative-In-Charge from Pfizer Inc., which had been signed under penalty of perjury by a corporate officer and the new designated representative-in-charge (DRIC). The form indicated that the prior DRIC, Cynthia Jones (EXC 19073), dissociated on February 1, 2022 and that Nelson Zamora-Ramos (DRL 40641) took over as the new DRIC the following day. However, DRL Zamora-Ramos was unable to be named as DRIC because he did not hold an EXC license. Pfizer Inc.'s Application for Change of Designated Representative-In-Charge was subsequently rejected. On March 14, 2023, the Board received an Application for Change of

Designated Representative-In-Charge from Pfizer Inc., which had been signed under penalty of perjury by a corporate officer and the new designated representative-in-charge (DRIC). The form indicated that the prior DRIC, Nelson Zamora-Ramos (DRL 40641), dissociated on March 1, 2023 and that Darren Nathan (EXC 23723) took over as the new DRIC the same day. Pfizer Inc. operated without a licensed DRIC for 392 days (February 2, 2022 – March 1, 2023).

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely July 23, 2023, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

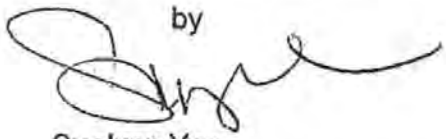
Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren

EXECUTIVE OFFICER

by



Suelynn Yee

Citation and Fine Analyst

INSTRUCTIONS

Read the Following Carefully and Thoroughly

You are hereby served with a Letter of Admonishment issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the admonishment process. In response to this Letter of Admonishment you may contest the admonishment and request an office conference.

CONTESTING THE LETTER OF ADMONISHMENT - Bus. Prof. Code § 4315 subd. (c)(1).

If you wish to contest your Letter of Admonishment you may request an informal office conference by completing and submitting the attached form according to the following instructions:

- Complete and mail attached "Request for Office Conference" form to the board office no later than 30 days from the service of this Letter of Admonishment, to the address at the bottom of the form.
- You may submit any declarations and/or documents pertinent to the subject matter of the Letter of Admonishment as attachments to the request form or they may be submitted by you at the office conference.
- You will be advised by the board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Letter of Admonishment that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Letter of Admonishment may be affirmed, modified or withdrawn. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Letter of Admonishment, is affirmed you will have 30 days from the date of the decision letter to submit any additional written corrective action plan information required. If the Letter of Admonishment is modified, the letter originally issued shall be considered withdrawn and a new letter will be issued. This decision shall be deemed to be the final administrative decision concerning the Letter of Admonishment.

If you have questions regarding any documents enclosed with the Letter of Admonishment, please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Mailing Address: State Board of Pharmacy
Attn: Suelynn Yee
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3013.

California State Board of Pharmacy

REQUEST FOR OFFICE CONFERENCE

Licensee: PFIZER INC

License No: OSD 4069

Citation Number : CI 2022 99946

I hereby acknowledge receipt of the Letter of Admonishment referenced above and notification of my rights to contest the citation.

Check ☐ I contest the Letter of Admonishment and request an Office Conference.

Check One:

☐ I contest the entire Letter of Admonishment or

☐ Specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

(Submit additional sheets if needed.)

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Daytime Number: (___) _____ Email Address: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: PFIZER INC OSD 4069
LETTER OF ADMONISHMENT CI 2022 99946

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On June 23, 2023, I served the attached:

Cover Letter, Instructions to Respondent, Letter of Admonishment, Request for Office Conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
PFIZER INC ATTN: ALBERT BOURLA, CEO 1855 SHELBY OAKS DR N MEMPHIS, TN 38134	7021 1970 0001 5375 3500

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 23, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

CO Grandparent Discipline

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

John W. Hickenlooper
Governor

Barbara J. Kelley
Executive
Director

March 1, 2011

Pfizer Inc, WHO 7193
Attn: Nate Underwood
1855 Shelby Oaks Dr North
Memphis, TN 38134

Pfizer Inc, WHO 7190
Attn: Wendell Wendling
One Pfizer Way, Bldg 200
Lees Summit, MO 64081

Pfizer Inc, WHO 7197
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer Inc, WHO 7194
Attn: Charles Thorwarth
100 Jefferson Road
Parsippany, NJ 07054

Pfizer Inc., WHO 7196
Attn: Tim Putman
1950 West Oaks Circle
Marietta, GA 30062

RE: Stipulation and Final Agency Order
Case #2011-0838, Case #2011-1101, Case #2011-0835, Case #2011-1136, Case #2011-0833

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATIONS OF PFIZER, INC., REGISTRATION NOS. WHO 7193, WHO 7190, WHO 7197, WHO 7194 AND WHO 7196,

Dear Designated Representatives:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective February 18, 2011.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
PDMP Administrator

Enclosure

cc: John C. Steele, Director, Office of Expedited Settlement
Brendan Sheehan, Esq., Pfizer, Inc.
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case Nos. 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATIONS OF PFIZER, INC., REGISTRATION NOS. WHO 7193, WHO 7190, WHO 7197, WHO 7194, AND WHO 7196,

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Pfizer, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registrations as non-resident prescription drug wholesalers, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent in 2011-000838 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 28, 2007, being issued registration number WHO 7193, and has been so registered at all times relevant to this disciplinary action.

3. Respondent in 2011-001101 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 26, 2007, being issued registration number WHO 7190, and has been so registered at all times relevant to this disciplinary action.

4. Respondent in 2011-000835 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on March 6, 2007, being issued registration number WHO 7197, and has been so registered at all times relevant to this disciplinary action.

5. Respondent in 2011-001136 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 28, 2007, being

issued registration number WHO 7194, and has been so registered at all times relevant to this disciplinary action.

6. Respondent in 2011-000833 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on March 6, 2007, being issued registration number WHO 7196, and has been so registered at all times relevant to this disciplinary action.

7. Respondent admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

8. Respondent failed to timely submit applications to the Board detailing changes in designated representatives and fees. In 2011-000838, 670 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-001101, 858 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-000835, 670 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-001136, 149 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-000833, 1,159 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

9. Respondent's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3)(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

10. The Board finds and concludes, and Respondent agrees, that based upon Respondent's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

11. **Fines with Surcharges.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00) in each case, 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833 (the "Cases"). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of each of these fines. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00) in each of the Cases. The total combined amount of Twenty Seven Thousand Five Hundred Dollars and No Cents ($27,500.00) shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

12. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

13. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

14. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

15. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

16. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a

court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent

Gregory A. Norr / Director, Global Logistics Compliance Dated: Feb 14, 2011
Authorized Representative / Title

Subscribed and sworn to before me in the County of Shelby, State of Tennessee, this 14th day of February, 2011 by Greg A. Norr, authorized representative of Pfizer, Inc., in each of the Cases.

My commission expires: My Commission Expires: October 7, 2014

Alice S. LeBlanc
Notary Public

ALICE S LEBLANC
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of February, 2011.

State Board of Pharmacy

BY: Wendy Anderson
~~Susan S. Martin~~ Wendy Anderson
~~Acting~~ Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 21st day of December 2010, addressed as follows:

Brendan Sheehan, Esq.
Pfizer, Inc.
235 E. 42nd St.
New York, NY 10017
(via email: Brendan.R.Sheehan@Pfizer.com)

[On Behalf Of:

Pfizer, Inc.
Attn: Nate Underwood
1855 Shelby Oaks Dr. No.
Memphis, TN 38134

Pfizer, Inc.
Attn: Wendell Wendling
One Pfizer Way, Bldg. 200
Lee's Summit, MO 64081

Pfizer, Inc.
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer, Inc.
Attn: Charles Thorwarth
100 Jefferson Rd.
Parsippany, NJ 07054

Pfizer, Inc.
Attn: Tim Putman
1950 W. Oaks Cir.
Marietta, GA 30062]

/s/ John C. Steele

John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this ~~28th~~ 1st day of ~~February~~ March 2011, addressed as follows:

Brendan Sheehan, Esq.
Pfizer, Inc.
235 E. 42nd St.
New York, NY 10017

[On Behalf Of:

Pfizer, Inc.
Attn: Nate Underwood
1855 Shelby Oaks Dr. No.
Memphis, TN 38134

Pfizer, Inc.
Attn: Wendell Wendling
One Pfizer Way, Bldg. 200
Lee's Summit, MO 64081

Pfizer, Inc.
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer, Inc.
Attn: Charles Thorwarth
100 Jefferson Rd.
Parsippany, NJ 07054

Pfizer, Inc.
Attn: Tim Putman
1950 W. Oaks Cir.
Marietta, GA 30062]

Agent of the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Corden Pharma GmbH
Address: Otto-Hahn-Strasse City: 68723 Plankstadt ~~State:~~ Germany ~~Zip:~~

Name: Sharp Packaging Services, LLC
Address: 7451 Keebler Way City: Allentown State: PA Zip: 18106

Name: AbbVie Inc.
Address: 100 Research Drive City: Worcester State: MA Zip: 01605

Name: Esteve Quimica S.A. (Celra)
Address: C/ del Ter, 94 City: Celra, Girona 17460 State: Spain Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Pfizer Investment Enterprises Holdings Pte. Ltd.
Corporation/Organization Name: Seagen Inc.
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: SGN@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA: 3002781621	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - 100% sole ownership		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A - No MDEG	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A - No MDEG	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Seagen Inc.

Facility Name

Susan E Grant

Print Name of Authorized Person Submitting Application

S E [illegible]

Original signature of Authorized Person (copies or stamps not accepted)

12/19/2024

Date

Board Use Only	Date Received: 1/17/25	Amount: $1000 Check 406

/ Drug Establishments Current Registration Site (default.cfm)

Drug Establishments Current Registration Site

New Search (default.cfm)

Search Results for **Seagen**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
SEAGEN INC.	3002781621	028484371	ANALYSIS; API MANUFACTURE;	21823 30th Drive SE, Bothell, Washington (WA) 98021, United States (USA)	12/31/2024

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Wednesday, Jan 10, 2024

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Proof of Labeler Code
0747

/ NDC (index.cfm)

National Drug Code Directory

Current through January 11, 2024

You have searched Finished drug products

Search Results: *'51144'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
ADCETRIS	51144-050-01	50 mg/10.5mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA125388	SEAGEN INC.	51144-050	brentuximab vedotin	BRENTUXIMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	08/25/2011	N/A	BLA
PADCEV	51144-020-01	20 mg/2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761137	SEAGEN INC.	51144-020	ENFORTUMAB VEDOTIN	ENFORTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	12/18/2019	N/A	BLA
PADCEV	51144-030-01	30 mg/3mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761137	SEAGEN INC.	51144-030	ENFORTUMAB VEDOTIN	ENFORTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	12/18/2019	N/A	BLA
TIVDAK	51144-003-01	40 mg/4mL	INJECTION, POWDER, FOR SOLUTION	INTRAVENOUS	BLA761208	Seagen Inc.	51144-003	tisotumab vedotin	TISOTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	09/20/2021	N/A	BLA
TUKYSA	51144-001-60	50 mg/1	TABLET	ORAL	NDA213411	SEAGEN INC.	51144-001	tucatinib	TUCATINIB	HUMAN PRESCRIPTION DRUG	04/17/2020	N/A	NDA
TUKYSA	51144-002-12	150 mg/1	TABLET	ORAL	NDA213411	SEAGEN INC.	51144-002	tucatinib	TUCATINIB	HUMAN PRESCRIPTION DRUG	04/17/2020	N/A	NDA

Officer List

Seagen®

December 13, 2023

To Whom It May Concern:

The below list is the current officer listing for Seagen Inc.'s pharmaceutical licensing:

Brian Gavin Byala – Vice President and Treasurer
Brian J McMahon – Vice President and Assistant Treasurer
Susan E Grant – Assistant Secretary

Company particulars

Seagen Inc.

Corporate Address: 21823 30th Drive SE, Bothell, WA 98021 USA
FEIN: 91-1874389
www.seagen.com

Drug Labeler Code: 51144
Incorporation State: DE
Incorporation Date: 07/15/1997

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
823	21823 30th Drive SE Bothell, WA 98021 County: Snohomish	3002781621	N/A - No CS	02848371	No	(425) 527-4000	(425) 527-4107

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	
Jean I. Liu	[redacted]	Chief Legal Officer and Secretary	No	*DR only for MT*
Susan Lynn Fletcher		Senior Director, Global Quality Operations		*For all states except MT*

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority
Pfizer Investment Enterprises Holdings Pte. Ltd.	10 Collyer Quay #10-01 Ocean Financial Centre 049315 Singapore		100%	

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority
Susan E Grant	[redacted]	Assistant Secretary	
Brian J McMahon		Vice President and Assistant Treasurer	
Brian Gavin Byala		Vice President & Treasurer	

REGISTERED AGENT IN ALL APPLICABLE STATES

Name
CT Corp

3PLS

Name	Address	Title	Prescribing Authority
Integrated Commercialization Solutions, LLC	420 International Blvd. Brooks, KY 40109		

Seagen Inc.

Integrated Commercialization Solutions, LLC

1195 Trademark Drive
Suite # 102
Reno, NV 89521

Formation Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SEAGEN INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SEAGEN INC." WAS INCORPORATED ON THE FIFTEENTH DAY OF JULY, A.D. 1997.

Jeffrey W. Bullock, Secretary of State

2774177 8300

SR# 20234201923

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204798843

Date: 12-13-23

Certificate of Merger
CHOW 0752

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"ARIS MERGER SUB, INC.", A DELAWARE CORPORATION,

WITH AND INTO "SEAGEN INC." UNDER THE NAME OF "SEAGEN INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE ON THE THIRTEENTH DAY OF DECEMBER, A.D. 2023, AT 5:21 O'CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE FOURTEENTH DAY OF DECEMBER, A.D. 2023 AT 12:01 O'CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

2774177 8100M
SR# 20234218209

Authentication: 204808739
Date: 12-13-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:21 PM 12/13/2023
FILED 05:21 PM 12/13/2023
SR 20234218209 - File Number 2774177

CERTIFICATE OF MERGER

OF

ARIS MERGER SUB, INC.
a Delaware corporation

WITH AND INTO

SEAGEN INC.,
a Delaware corporation

December 13, 2023

Pursuant to Title 8, Section 251(c) of the Delaware General Corporation Law (the "DGCL"), Seagen Inc., a corporation organized and existing under the laws of the State of Delaware (the "Company"), hereby certifies as follows:

FIRST: The name and state of incorporation of each of the constituent corporations (the "Constituent Corporations") to this Merger (as defined below) are as follows:

Name	State of Incorporation
Aris Merger Sub, Inc.	Delaware
Seagen Inc.	Delaware

SECOND: An Agreement and Plan of Merger, dated as of March 12, 2023 (the "Agreement"), by and among the Company, Pfizer Inc., a Delaware corporation ("Parent"), and Aris Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"), setting forth the terms and conditions of the merger of Merger Sub with and into the Company (the "Merger"), has been approved, adopted, executed and acknowledged by each of the Constituent Corporations in accordance with Section 251 of the DGCL.

THIRD: The name of the corporation surviving the Merger is "Seagen Inc." (the "Surviving Corporation").

FOURTH: The certificate of incorporation of the Surviving Corporation shall be amended and restated to read in its entirety as set forth on Exhibit A attached hereto and, as so amended and restated, will be the certificate of incorporation of the Surviving Corporation until thereafter duly amended as provided therein or by applicable law.

FIFTH: The executed Agreement is on file at an office of the Surviving Corporation located at 21823 30th Drive SE, Bothell, Washington 98021.

SIXTH: A copy of the Agreement will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either of the Constituent Corporations.

SEVENTH: The Merger shall be effective as of 12:01 a.m., Eastern Time, on December 14, 2023.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Seagen Inc. has caused this Certificate of Merger to be executed in its corporate name by an authorized officer as of the date first above written.

SEAGEN INC.

By: DocuSigned by:
8ED14BDB77094BA...

Name: Jean I. Liu
Title: Chief Legal Officer

Exhibit A

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF SEAGEN INC.

ARTICLE I

The name of the corporation is: Seagen Inc. (the "Corporation").

ARTICLE II

The address, including street, number, city, and county of the registered office of the Corporation in the State of Delaware is the Corporation Trust Center, 1209 Orange Street, City of Wilmington, County of New Castle, State of Delaware 19801; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation shall be to engage in any lawful act or activity for which corporations may be organized and incorporated under the General Corporation Law of the State of Delaware ("DGCL").

ARTICLE IV

Section 1. Corporation shall be authorized to issue 1,000 shares of capital stock, all of which 1,000 shares shall be shares of common stock, par value $0.01 per share (the "Common Stock").

Section 2. Except as otherwise provided by law, the Common Stock shall have the exclusive right to vote for the election of directors and for all other purposes. Each share of the Common Stock shall have one vote and the Common Stock shall vote together as a single class.

ARTICLE V

Any one or more directors may be removed, with or without cause, by the vote or written consent of the holders of a majority of the issued and outstanding shares of capital stock of the Corporation entitled to be voted in the election of directors.

ARTICLE VI

In furtherance and not in limitation of those powers conferred by law, the board of directors of the Corporation (the "Board") is expressly authorized and empowered to make, alter and repeal the by-laws of the Corporation (the "By-Laws").

ARTICLE VII

Meetings of the stockholders shall be held at such place, within or without the State of Delaware as may be designated by, or in the manner provided in, the By-Laws or, if not so designated, at the registered office of the Corporation in the State of Delaware, Elections of directors need not be by written ballot unless and to the extent that the By-Laws so provide.

ARTICLE VIII

The Corporation reserves the right at any time from time to time to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, and any other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereinafter prescribed by law, and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

ARTICLE IX

(A) To the fullest extent permitted by the DGCL, as the same may be amended from time to time, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is hereafter amended to authorize, with the approval of a corporation's stockholders, further reductions in the liability of a corporation's directors for breach of fiduciary duty, then a director of the Corporation shall not be liable for any such breach to the fullest extent permitted by the DGCL, as so amended.

(B) Any repeal or modification of the foregoing provisions of this Article IX shall not adversely affect any right or protection of a director of the Corporation with respect to any acts or omissions of such director occurring prior to such repeal or modification.

ARTICLE X

(A) To the fullest extent permitted by applicable law, the Corporation is also authorized to provide indemnification of (and advancement of expenses to) such agents (and any other persons to which Delaware law permits the Corporation to provide indemnification) through By-Law provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the DGCL, subject only to limits created by applicable Delaware law (statutory or non-statutory), with respect to actions for breach of duty to a corporation, its stockholders, and others.

(B) Any repeal or modification of any of the foregoing provisions of this Article X shall not adversely affect any right or protection of a director, officer, agent or other person existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director, officer or agent occurring prior to such repeal or modification.

Washington State Department of Health

This organization

Seagen Inc.

is authorized by RCW 18.64 to have a

Pharmaceutical Manufacturer License

Washington State Department of HEALTH

Operated by: **Seagen Inc.**

Located at: **21823 30th Dr SE**
Bothell, WA 98021-3907

Secretary

Status
ACTIVE

Credential Number
PHMF.FX.60961629

Effective Date
10/01/2023

Expiration Date
09/30/2024

Bond Continuation

CONTINUATION CERTIFICATE

To be attached to and form part of Pharmaceutical Wholesaler Surety Bond

Bond Number: 57BSBIA4433

Bond Amount: $25,000.00

On behalf of Principal: Seagen Inc.

Issued by Surety: Hartford Fire Insurance Company

In favor of Obligee: State of Nevada

Bond Effective Date: February 1, 2020

The Surety hereby certifies that this Bond is continued in full force and effect subject to all covenants and conditions of said Bond for the period **February 1, 2024 to February 1, 2025**. Said Bond has been continued in force upon the express condition that the full extent of the Surety's liability under said Bond, and this and all continuations hereof, for any loss or series of losses occurring during the entire time the Surety remains on said Bond, shall in no event exceed the penal sum of the Bond.

IN WITNESS WHEREOF the Surety has caused this instrument to be duly signed, sealed and

Dated as of the 15th day of December, 2023.

Hartford Fire Insurance Company

By: Valerie Takeuchi
Valerie Takeuchi, Attorney-in-Fact

HARTFORD FIRE INSURANCE CO
INCORPORATED 1810

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: WOODRUFF SAWYER & COMPANY
Agency Code: 57-554795

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Nerissa S. Bartolome, Joan DeLuca, Patrick R Diebel, Lucy M. Dunham, Andrew S. Holloway, Kelly Holtemann, Christopher M. Howell, Thomas E. Hughes, Mark M. Munekawa, Zachary V. Overbay, Christina Parsons, Rossio Polio, Karen Rhodes, Yvonne Roncagliolo, Charles R. Shoemaker, Valerie Takeuchi of SAN FRANCISCO, California

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of December 15, 2023

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seagen Inc.

Pharmacy/Wholesaler License # (if applicable): WH02809

Physical Address: 21823 30th Drive SE

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.seagen.com

Licensing Company Email: SGN@slsny.com

Section 2: Personal Information

First: Susan Middle: Lynn Last: Fletcher

Alias(es, nicknames, name changes, etc.): Susi (nickname), Susan Lothner (maiden name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Seattle State: WA Zip: 98117

Telephone: [redacted] Email: sfletcher@seagen.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Gustavus Adolphus College		09/1991 - 06/1995	
Address	City	State	Zip
800 W College Ave	St Peter	MN	56082
Diploma/Degree obtained, if any			
Bachelor of Arts, Biochemistry and Molecular Biology			
School Name		From - To (MM/YY – MM/YY)	
Duluth East High School		09/1987 - 06/1991	
Address	City	State	Zip
2900 E 4th Street	Duluth	MN	55812
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/1998 - Present	[redacted]	Seattle	WA	98117
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Seagen Inc.			2011 - Present	
Business Address		**City**	**State**	**Zip**
21823 30th Drive SE		Bothell	WA	98021
Phone	**Title**		**Number of Employed Hours**	
(425) 527-4000	Senior Director, Global Quality Operations		~ 26,867 hrs	
Description of Duties				
Responsible for leadership of Quality Operations areas. Responsible for and directly manages the leadership of Local Quality Operations. Implement and manage the GMP compliant quality programs for ensuring compliant product supply in adherence to current FDA Guidelines. Provide strategic direction, oversight and staff management in providing quality oversight of shipping, receiving, storage and material management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Susan Lynn Fletcher, **certify that as the designated representative for**

Seagen Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AF I am at least 21 years of age;
3. AF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Susan Lynn Fletcher
Print Name (First, Last)

Susan L. Fletcher
Original Signature (electronic, copies or stamps not accepted)

14 DEC 2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Lynn Fletcher

Print Name (First, Last)

Susan L. Fletcher

Original Signature (electronic, copies or stamps not accepted)

14DEC2023

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of Snohomish

I, Susan Fletcher, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Susan L. Fletcher

Original Signature

Susan Lynn Fletcher

14DEC2023

Date

Subscribed and Sworn to before me this 14 day of December.

Tammy Funk

Notary Public Signature

TAMMY FUNK
Notary Public
State of Washington
Commission # 159243
My Comm. Expires Feb 6, 2028

(Seal)

Employee List

0769

First Name	Last Name
B1 Canyon Park, 21823 30th Dr. SE	
Sherif	Abdelhamed
Martin	Akyem
Kaveh	Alizadeh
Sean	Allred
Sarah	Anderson
Aleena	Arakaki
Roger	Ashmus
Megan	Atkins
Allyson	Bakan
Erica	Ballou
Noah	Bindman
Brittney	Blackburn
Scott	Blackburn
Gabriele	Blahnik-Fagan
Teri	Blevins
Tim	Bovee
Jera	Brandvig
Maddy	Burcher
Kelli	Burley
Sara	Carbonetti
Kristen	Cardinal
Markus	Carlson
Chris	Carosino
Sarah	Carratt
Katie	Caspary
Yufei	Chen
Dayna	Clarke
Julia	Cochran
Kerrie	Collins
Michelle	Cook Sangar
Garrett	Cornelison

First Name	Last Name
Jamie	Mitchell
Philip	Moquist
Eliana	Moskovitz
Briana	Mulligan
Andrea	Musa
James	Mutschler
Lydia	Navarrete-Galvan
Albina	Nesterova
Liem	Nguyen
Tyler	Nicholas
Khrystyna	North
Kathleen	Olivas
Devra	Olson
Keely	Oltion
Nick	Parekh
LaKeisha	Perkins
Norman	Peterson
Adam	Peterson
Paromita	Raha
Matt	Rathgeber
Niels	Rekers
Ashley	Rennie
Alejandro	Rizo
Rory	Rohm
Kathy	Rohrbach
Kyle	Romine
Catalina	Sakai
Bobby	Santos
Leah	Schmidt
Alyssa	Schwartz
Peter	Senter
Laila	Shehata

Liam	Coyle
Joel	Courter
KC	Crowder
Elizabeth	Cummins
Kevin	Daze
Lindsay	Deis Huffman
Joe	Dekker
Ana	Dinca
Lindsay	Dotloe
Brendan	Drouhard
Casey	Franklin
Andee	Friant
Kristen	Gahnberg
Nic	Garcia
Kali	Garland
Mark	Gilchrist
Jaimie	Granger
Betsy	Gray
Marlena	Gray
Jonathan	Grey
Bryan	Grogan
Sylvia	Grosch
David	Gruber
Lupe	Gutierrez
Julie	Hahn
Kat	Hahn
Joseph	Hamilton
Keagen	Hansen
Kendal	Harr
Jae	Hartsuyker
Renee	Hein
Florian	Heinkel
Kelly	Hensley

Andrey	Shuvarikov
Heather	Sigurjonsson
Jess	Simmons
Kaleb	Smith
Katie	Snead
Nicole	Stevens
Claire	Stoffers
Ivan	Stone
Hao	Sun
Django	Sussman
Chris	Swanson
Giacomo	Tampella
Janelle	Taylor
Vivian	Trang
Jennifer	Tsoung
Michelle	Ulrich
Barrett	Updegraff
Kung-Pern	Wang
Anna Leigh	White
Kelsi	Willis
Neva	Wilson
Chun-Shu	Wong
Jenn	Wright
Kellee	Xing
Sunny	Yan
Ashton	Yang
Xiao Di (Cindy)	Yang
Narayana	Yeddula
Patrick	Younan
Aleena	Young
Roma	Yumul
Weiping	Zeng
Amy	Zhang

Victor	Hermand
John	Hernandez Villanueva
Debby	Higginbotham
Adam	Hill
Sabrina	Hock
Haley	Holliday
Andrew	Holtzen
Rachael	Hu
Li-Ya	Huang
Julia	Huck
Reice	James
Remi	Jawando
Marcell	Jenkins
Steven	Jin
Dora	Kadish
Nanna Hansen	Katdare
Samantha	Michaels
Meghan	Zuck
Austin	Head

Janet	Zheng
Andrew	Olk
Kristin	Petkavich
Parul	Katoch
Rachel	Katz
Kerry	Klussman
Brian	Knapp
Megan	Kufeld
Anita	Kulukian
Daria	Kurandina
John	Kwon
Robert	Lawrence
Cherry	Leung
Christina	Leverich
CB	Lim
Gina	LoMastro
Sasha	Lucas
Ryan	Lyski
Rebecca	Mazahreh
Erica	McKinney

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

4

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03245	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Seagen Inc.

Physical Address: 3450 Monte Villa Parkway

City: Bothell State: WA Zip: 98021

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.seagen.com

Name of Designated Representative (DR): Ryan Ken Takeya

Licensing Company Email: SGNMVP@slsny.com DR Email: rtakeya@seagen.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Drugs (Biologics)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Manufacturers		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2023	N/A	CA	Sacramento	Sacramento County
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
CI 2022 99946	California State Board of Pharmacy			
Reason/Charge				
Letter of Admonishment				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
N/A	N.A			
Name of Business/Industry/Entity				
Pfizer Inc				

Provide explanation below:

Grandparent Company, Pfizer Inc. received a Letter of Admonition from the CA Board of Pharmacy for failing to notify the board of a new Designated Representative within the required 30 days. Please see the attached Letter of Admonishment and response from client.

S E Susan E Grant

Original Signature (electronic, copies or stamps not accepted)

12/4/2023

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/14/2011	N/A	CO	Denver	Denver County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
#2011-0838, #2011-1101, #2011-0835, #2011-1136, #2011-0833	Colorado State Board of Pharmacy

Reason/Charge
Failure to report a Change of DR within Colorado's filing deadline

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
N/A	N/A

Name of Business/Industry/Entity
Pfizer Inc

Provide explanation below:

Please be advised that during September/October of 2010, Grandparent Company, Pfizer Inc received complaints from the Colorado Department of Regulatory Agencies (DORA) related to the timeliness in reporting a change to the designated representative at 5 of the Pfizer distribution site locations. Pfizer has provided DORA with all of the required designated representative change information and has settled all of the complaints. The matter is now resolved and all of the licenses involved are currently in good standing.

S. C. Susan E Grant

Original Signature (electronic, copies or stamps not accepted)

12/14/2027

Date

letter of Admonishment

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

June 23, 2023

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

PFIZER INC
ATTN: ALBERT BOURLA, CEO
1855 SHELBY OAKS DR N
MEMPHIS, TN 38134

RE: CI 2022 99946
PFIZER INC
OSD 4069

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 4161(j) - A nonresident wholesaler or non resident third-party logistics provider shall identify and notify the board of a new designated representative in charge ceases to be the designated representative in charge

Failure to Notify within 30 Days – Business and Professions Code section 4161(j) requires a nonresident wholesaler or nonresident third-party logistics provider to identify and notify the Board of a new designated representative-in-charge (DRIC) or responsible manager (RMG) within 30 days of the date that the prior DRIC or RMG ceases to be the DRIC or RMG. Specifically, on March 3, 2022 the Board received an Application for Change of Designated Representative-In-Charge from Pfizer Inc., which had been signed under penalty of perjury by a corporate officer and the new designated representative-in-charge (DRIC). The form indicated that the prior DRIC, Cynthia Jones (EXC 19073), dissociated on February 1, 2022 and that Nelson Zamora-Ramos (DRL 40641) took over as the new DRIC the following day. However, DRL Zamora-Ramos was unable to be named as DRIC because he did not hold an EXC license. Pfizer Inc.'s Application for Change of Designated Representative-In-Charge was subsequently rejected. On March 14, 2023, the Board received an Application for Change of

Designated Representative-In-Charge from Pfizer Inc., which had been signed under penalty of perjury by a corporate officer and the new designated representative-in-charge (DRIC). The form indicated that the prior DRIC, Nelson Zamora-Ramos (DRL 40641), dissociated on March 1, 2023 and that Darren Nathan (EXC 23723) took over as the new DRIC the same day. Pfizer Inc. operated without a licensed DRIC for 392 days (February 2, 2022 – March 1, 2023).

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely July 23, 2023, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

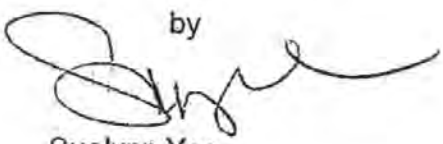
Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren

EXECUTIVE OFFICER

by



Suelynn Yee

Citation and Fine Analyst

INSTRUCTIONS

Read the Following Carefully and Thoroughly

You are hereby served with a Letter of Admonishment issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the admonishment process. In response to this Letter of Admonishment you may contest the admonishment and request an office conference.

CONTESTING THE LETTER OF ADMONISHMENT - Bus. Prof. Code § 4315 subd. (c)(1).

If you wish to contest your Letter of Admonishment you may request an informal office conference by completing and submitting the attached form according to the following instructions:

- Complete and mail attached "Request for Office Conference" form to the board office no later than 30 days from the service of this Letter of Admonishment, to the address at the bottom of the form.
- You may submit any declarations and/or documents pertinent to the subject matter of the Letter of Admonishment as attachments to the request form or they may be submitted by you at the office conference.
- You will be advised by the board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Letter of Admonishment that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Letter of Admonishment may be affirmed, modified or withdrawn. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Letter of Admonishment, is affirmed you will have 30 days from the date of the decision letter to submit any additional written corrective action plan information required. If the Letter of Admonishment is modified, the letter originally issued shall be considered withdrawn and a new letter will be issued. This decision shall be deemed to be the final administrative decision concerning the Letter of Admonishment.

If you have questions regarding any documents enclosed with the Letter of Admonishment, please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Mailing Address: State Board of Pharmacy
Attn: Suelynn Yee
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3013.

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: PFIZER INC

License No: OSD 4069

Citation Number : CI 2022 99946

I hereby acknowledge receipt of the Letter of Admonishment referenced above and notification of my rights to contest the citation.

Check ☐ I contest the Letter of Admonishment and request an Office Conference.

Check One:

☐ I contest the entire Letter of Admonishment or

☐ Specific violations for the following reasons (list each violation with your specific reason):

_____

_____

_____

_____

_____

_____

(Submit additional sheets if needed.)

Name: _____

Signature: _____ Dated: _____

Address of Service: _____

City: _____ State: _____ Zip: _____

Daytime Number: (___) _____ Email Address: (___) _____

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: PFIZER INC OSD 4069
LETTER OF ADMONISHMENT CI 2022 99946

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On June 23, 2023, I served the attached:

Cover Letter, Instructions to Respondent, Letter of Admonishment, Request for Office Conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

NAME	CERTIFIED MAIL NO
PFIZER INC ATTN: ALBERT BOURLA, CEO 1855 SHELBY OAKS DR N MEMPHIS, TN 38134	7021 1970 0001 5375 3500

I declare under penalty of perjury that the forgoing is true and correct.

Executed on June 23, 2023, at Sacramento, California.

DECLARANT
Suelynn Yee
Citation and Fine Analyst

Response

Pfizer Inc
1855 Shelby Oaks Drive North
Memphis, TN 38134-7401
Tel 901 380-6368
Fax 800-310-4437

Pfizer Breakthroughs that change patients' lives®

Darren Nathan
Compliance Lead

July 19, 2023

California State Board of Pharmacy
Attn: Suelynn Yee, Citation and Fine Analyst
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Re: CI 2022 99946
Pfizer Inc OSD 4069

Dear Analyst Yee,

I am writing to formally acknowledge the receipt of your Letter of Admonishment issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California, dated June 23, 2023.

Pfizer takes this matter very seriously and strives to maintain a high level of compliance with the California Board of Pharmacy regulations going forward.

It is our understanding that I am currently the Designated Representative in Charge for the license in question and that the firm is now in compliance with Business and Professions Code § 4315; 4161(j).

A Designated Representative in Charge application for Nelson Zamora-Ramos was mailed to your office on March 9, 2023. Once his application has been approved, we will submit a request to add him as a Designated Representative in Charge for this license in addition to myself. Any assistance in processing the March 9th application will be most appreciated.

Should you have any further guidance, please do not hesitate to contact me at 901-380-6368.

Sincerely yours,

DocuSigned by:
Darren Nathan
Signer Name: Darren Nathan
Signing Reason: I am the author of this document
Signing Time: 19-Jul-2023 | 3:40:27 PM EDT
E1D3E5C9AE554407A00BFD5E7624F0CE

Darren Nathan
Compliance Lead

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

John W. Hickenlooper
Governor

Barbara J. Kelley
Executive
Director

March 1, 2011

Pfizer Inc, WHO 7193
Attn: Nate Underwood
1855 Shelby Oaks Dr North
Memphis, TN 38134

Pfizer Inc, WHO 7190
Attn: Wendell Wendling
One Pfizer Way, Bldg 200
Lees Summit, MO 64081

Pfizer Inc, WHO 7197
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer Inc, WHO 7194
Attn: Charles Thorwarth
100 Jefferson Road
Parsippany, NJ 07054

Pfizer Inc., WHO 7196
Attn: Tim Putman
1950 West Oaks Circle
Marietta, GA 30062

RE: Stipulation and Final Agency Order
Case #2011-0838, Case #2011-1101, Case #2011-0835, Case #2011-1136, Case #2011-0833

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATIONS OF PFIZER, INC., REGISTRATION NOS. WHO 7193, WHO 7190, WHO 7197, WHO 7194 AND WHO 7196,

Dear Designated Representatives:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective February 18, 2011.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
PDMP Administrator

Enclosure

cc: John C. Steele, Director, Office of Expedited Settlement
Brendan Sheehan, Esq., Pfizer, Inc.
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case Nos. 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATIONS OF PFIZER, INC., REGISTRATION NOS. WHO 7193, WHO 7190, WHO 7197, WHO 7194, AND WHO 7196,

Respondents.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Pfizer, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registrations as non-resident prescription drug wholesalers, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent in 2011-000838 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 28, 2007, being issued registration number WHO 7193, and has been so registered at all times relevant to this disciplinary action.

3. Respondent in 2011-001101 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 26, 2007, being issued registration number WHO 7190, and has been so registered at all times relevant to this disciplinary action.

4. Respondent in 2011-000835 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on March 6, 2007, being issued registration number WHO 7197, and has been so registered at all times relevant to this disciplinary action.

5. Respondent in 2011-001136 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on February 28, 2007, being

issued registration number WHO 7194, and has been so registered at all times relevant to this disciplinary action.

6. Respondent in 2011-000833 was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on March 6, 2007, being issued registration number WHO 7196, and has been so registered at all times relevant to this disciplinary action.

7. Respondent admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

8. Respondent failed to timely submit applications to the Board detailing changes in designated representatives and fees. In 2011-000838, 670 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-001101, 858 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-000835, 670 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-001136, 149 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received. In 2011-000833, 1,159 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

9. Respondent's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3)(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

10. The Board finds and concludes, and Respondent agrees, that based upon Respondent's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

11. **Fines with Surcharges.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00) in each case, 2011-000838, 2011-001101, 2011-000835, 2011-001136, and 2011-000833 (the "Cases"). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of each of these fines. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00) in each of the Cases. The total combined amount of Twenty Seven Thousand Five Hundred Dollars and No Cents ($27,500.00) shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

12. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

13. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order and probation, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

14. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

15. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

16. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a

court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent

Gregory A. Norr / Director, Global Logistics Compliance Dated: Feb 14, 2011
Authorized Representative / Title

Subscribed and sworn to before me in the County of Shelby, State of Tennessee, this 14th day of February, 2011 by Greg A. Norr, authorized representative of Pfizer, Inc., in each of the Cases.

My commission expires: My Commission Expires: October 7, 2014

Alice S. LeBlanc
Notary Public

ALICE S LEBLANC
STATE OF TENNESSEE
NOTARY PUBLIC
SHELBY COUNTY

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of February, 2011.

State Board of Pharmacy

BY: Wendy Anderson
~~Susan S. Martin~~ Wendy Anderson
~~Acting~~ Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 21st day of December 2010, addressed as follows:

Brendan Sheehan, Esq.
Pfizer, Inc.
235 E. 42nd St.
New York, NY 10017
(via email: Brendan.R.Sheehan@Pfizer.com)

[On Behalf Of:

Pfizer, Inc.
Attn: Nate Underwood
1855 Shelby Oaks Dr. No.
Memphis, TN 38134

Pfizer, Inc.
Attn: Wendell Wendling
One Pfizer Way, Bldg. 200
Lee's Summit, MO 64081

Pfizer, Inc.
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer, Inc.
Attn: Charles Thorwarth
100 Jefferson Rd.
Parsippany, NJ 07054

Pfizer, Inc.
Attn: Tim Putman
1950 W. Oaks Cir.
Marietta, GA 30062]

/s/ John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this ~~28th~~ 1st day of ~~February~~ March 2011, addressed as follows:

Brendan Sheehan, Esq.
Pfizer, Inc.
235 E. 42nd St.
New York, NY 10017

[On Behalf Of:

Pfizer, Inc.
Attn: Nate Underwood
1855 Shelby Oaks Dr. No.
Memphis, TN 38134

Pfizer, Inc.
Attn: Wendell Wendling
One Pfizer Way, Bldg. 200
Lee's Summit, MO 64081

Pfizer, Inc.
Attn: Elizabeth Reische
1025 Sandhill Rd.
Reno, NV 89521

Pfizer, Inc.
Attn: Charles Thorwarth
100 Jefferson Rd.
Parsippany, NJ 07054

Pfizer, Inc.
Attn: Tim Putman
1950 W. Oaks Cir.
Marietta, GA 30062]

Agent of the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Sartorius North America HQ
Address: 656 Johnson Avenue City: Bohemia State: NY Zip: 11716
Name: VWR Headquarters
Address: 100 Mastonford Rd City: Radnor State: PA Zip: 19087
Name: Cytiva Headquarters
Address: 100 Results way City: Marlborough State: MA Zip: 01752
Name: PALL Headquarters
Address: 25 Harbor Park Drive City: Port Washington State: NY Zip: 11050

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Pfizer Investment Enterprises Holdings Pte. Ltd.
Corporation/Organization Name: Seagen Inc.
Mailing Address: c/o State License Servicing, 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: 845-544-2482 Email: SGN@slsny.con
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA: 3002781621	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - 100% sole ownership		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A - No CS	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A - No MDEG	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A - No MDEG	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Seagen Inc.

Facility Name

Susan E Grant

Print Name of Authorized Person Submitting Application

S. E. G

Original signature of Authorized Person (copies or stamps not accepted)

12/4/2023

Date

Board Use Only	Date Received: 1/17/24	Amount: $1000 - check 408

Proof of Labeler Code
0795

/ NDC (index.cfm)

National Drug Code Directory

Current through January 11, 2024

Verified
1/26/24

You have searched Finished drug products

Search Results: '51144'

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category
ADCETRIS	51144-050-01	50 mg/10.5mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA125388	SEAGEN INC.	51144-050	brentuximab vedotin	BRENTUXIMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	08/25/2011	N/A	BLA
PADCEV	51144-020-01	20 mg/2mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761137	SEAGEN INC.	51144-020	ENFORTUMAB VEDOTIN	ENFORTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	12/18/2019	N/A	BLA
PADCEV	51144-030-01	30 mg/3mL	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS	BLA761137	SEAGEN INC.	51144-030	ENFORTUMAB VEDOTIN	ENFORTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	12/18/2019	N/A	BLA
TIVDAK	51144-003-01	40 mg/4mL	INJECTION, POWDER, FOR SOLUTION	INTRAVENOUS	BLA761208	Seagen Inc.	51144-003	tisotumab vedotin	TISOTUMAB VEDOTIN	HUMAN PRESCRIPTION DRUG	09/20/2021	N/A	BLA
TUKYSA	51144-001-60	50 mg/1	TABLET	ORAL	NDA213411	SEAGEN INC.	51144-001	tucatinib	TUCATINIB	HUMAN PRESCRIPTION DRUG	04/17/2020	N/A	NDA
TUKYSA	51144-002-12	150 mg/1	TABLET	ORAL	NDA213411	SEAGEN INC.	51144-002	tucatinib	TUCATINIB	HUMAN PRESCRIPTION DRUG	04/17/2020	N/A	NDA

Officer List

Seagen®

December 13, 2023

To Whom It May Concern:

The below list is the current officer listing for Seagen Inc.'s pharmaceutical licensing:

Brian Gavin Byala – Vice President and Treasurer
Brian J McMahon – Vice President and Assistant Treasurer
Susan E Grant – Assistant Secretary

Seagen Inc.

Corporate Address: 21823 30th Drive SE, Bothell, WA 98021 USA
FEIN: 91-1874389
www.seagen.com

Drug Labeler Code: 51144
Incorporation State: DE
Incorporation Date: 07/15/1997

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
MVP	3450 Monte Villa Parkway Bothell , WA 98021 County: Sonomish	3002781621	N/A - No CS		No	(425) 686-6831	(425) 527-4001

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Ryan Ken Takeya	[redacted]	Sr. Director, Manufacturing, Site Head	No	[redacted]		*ll States*

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Pfizer Investment Enterprises Holdings Pte. Ltd.	10 Collyer Quay #10-01 Ocean Financial Centre 049315 Singapore	N/A	100%	N/A	N/A	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Susan E Grant	[redacted]	Assistant Secretary		[redacted]		
Brian J McMahon		Vice President and Assistant Treasurer				
Brian Gavin Byala		Vice President & Treasurer				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corp			

Company Particulars

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SEAGEN INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SEAGEN INC." WAS INCORPORATED ON THE FIFTEENTH DAY OF JULY, A.D. 1997.

Jeffrey W. Bullock, Secretary of State

2774177 8300

SR# 20234201923

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204798843

Date: 12-13-23

Firmation Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SEAGEN INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTEENTH DAY OF DECEMBER, A.D. 2023.

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SR# 20234201923

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204798843

Date: 12-13-23

Certificate of Merger
CHOW Docs

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF MERGER, WHICH MERGES:

"ARIS MERGER SUB, INC.", A DELAWARE CORPORATION,

WITH AND INTO "SEAGEN INC." UNDER THE NAME OF "SEAGEN INC.", A CORPORATION ORGANIZED AND EXISTING UNDER THE LAWS OF THE STATE OF DELAWARE, AS RECEIVED AND FILED IN THIS OFFICE ON THE THIRTEENTH DAY OF DECEMBER, A.D. 2023, AT 5:21 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF MERGER IS THE FOURTEENTH DAY OF DECEMBER, A.D. 2023 AT 12:01 O'CLOCK A.M.

2774177 8100M
SR# 20234218209

Authentication: 204808739
Date: 12-13-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:21 PM 12/13/2023
FILED 05:21 PM 12/13/2023
SR 20234218209 - File Number 2774177

CERTIFICATE OF MERGER

OF

ARIS MERGER SUB, INC.
a Delaware corporation

WITH AND INTO

SEAGEN INC.,
a Delaware corporation

December 13, 2023

Pursuant to Title 8, Section 251(c) of the Delaware General Corporation Law (the "DGCL"), Seagen Inc., a corporation organized and existing under the laws of the State of Delaware (the "Company"), hereby certifies as follows:

FIRST: The name and state of incorporation of each of the constituent corporations (the "Constituent Corporations") to this Merger (as defined below) are as follows:

Name	State of Incorporation
Aris Merger Sub, Inc.	Delaware
Seagen Inc.	Delaware

SECOND: An Agreement and Plan of Merger, dated as of March 12, 2023 (the "Agreement"), by and among the Company, Pfizer Inc., a Delaware corporation ("Parent"), and Aris Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Parent ("Merger Sub"), setting forth the terms and conditions of the merger of Merger Sub with and into the Company (the "Merger"), has been approved, adopted, executed and acknowledged by each of the Constituent Corporations in accordance with Section 251 of the DGCL.

THIRD: The name of the corporation surviving the Merger is "Seagen Inc." (the "Surviving Corporation").

FOURTH: The certificate of incorporation of the Surviving Corporation shall be amended and restated to read in its entirety as set forth on Exhibit A attached hereto and, as so amended and restated, will be the certificate of incorporation of the Surviving Corporation until thereafter duly amended as provided therein or by applicable law.

FIFTH: The executed Agreement is on file at an office of the Surviving Corporation located at 21823 30th Drive SE, Bothell, Washington 98021.

SIXTH: A copy of the Agreement will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either of the Constituent Corporations.

SEVENTH: The Merger shall be effective as of 12:01 a.m., Eastern Time, on December 14, 2023.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, Seagen Inc. has caused this Certificate of Merger to be executed in its corporate name by an authorized officer as of the date first above written.

SEAGEN INC.

By: DocuSigned by:
8ED148D877094BA...

Name: Jean I. Liu
Title: Chief Legal Officer

Exhibit A

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF SEAGEN INC.

ARTICLE I

The name of the corporation is: Seagen Inc. (the "Corporation").

ARTICLE II

The address, including street, number, city, and county of the registered office of the Corporation in the State of Delaware is the Corporation Trust Center, 1209 Orange Street, City of Wilmington, County of New Castle, State of Delaware 19801; and the name of the registered agent of the Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE III

The purpose of the Corporation shall be to engage in any lawful act or activity for which corporations may be organized and incorporated under the General Corporation Law of the State of Delaware ("DGCL").

ARTICLE IV

Section 1. Corporation shall be authorized to issue 1,000 shares of capital stock, all of which 1,000 shares shall be shares of common stock, par value $0.01 per share (the "Common Stock").

Section 2. Except as otherwise provided by law, the Common Stock shall have the exclusive right to vote for the election of directors and for all other purposes. Each share of the Common Stock shall have one vote and the Common Stock shall vote together as a single class.

ARTICLE V

Any one or more directors may be removed, with or without cause, by the vote or written consent of the holders of a majority of the issued and outstanding shares of capital stock of the Corporation entitled to be voted in the election of directors.

ARTICLE VI

In furtherance and not in limitation of those powers conferred by law, the board of directors of the Corporation (the "Board") is expressly authorized and empowered to make, alter and repeal the by-laws of the Corporation (the "By-Laws").

ARTICLE VII

Meetings of the stockholders shall be held at such place, within or without the State of Delaware as may be designated by, or in the manner provided in, the By-Laws or, if not so designated, at the registered office of the Corporation in the State of Delaware, Elections of directors need not be by written ballot unless and to the extent that the By-Laws so provide.

ARTICLE VIII

The Corporation reserves the right at any time from time to time to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, and any other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereinafter prescribed by law, and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article.

ARTICLE IX

(A) To the fullest extent permitted by the DGCL, as the same may be amended from time to time, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is hereafter amended to authorize, with the approval of a corporation's stockholders, further reductions in the liability of a corporation's directors for breach of fiduciary duty, then a director of the Corporation shall not be liable for any such breach to the fullest extent permitted by the DGCL, as so amended.

(B) Any repeal or modification of the foregoing provisions of this Article IX shall not adversely affect any right or protection of a director of the Corporation with respect to any acts or omissions of such director occurring prior to such repeal or modification.

ARTICLE X

(A) To the fullest extent permitted by applicable law, the Corporation is also authorized to provide indemnification of (and advancement of expenses to) such agents (and any other persons to which Delaware law permits the Corporation to provide indemnification) through By-Law provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the DGCL, subject only to limits created by applicable Delaware law (statutory or non-statutory), with respect to actions for breach of duty to a corporation, its stockholders, and others.

(B) Any repeal or modification of any of the foregoing provisions of this Article X shall not adversely affect any right or protection of a director, officer, agent or other person existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director, officer or agent occurring prior to such repeal or modification.

Washington State Department of Health

This organization

Seagen Inc.

is authorized by RCW 18.64 to have a

Pharmaceutical Manufacturer License

Operated by: **Seagen Inc.**

Located at: **3450 Monte Villa Pkwy**
Bothell, WA 98021-8906

Secretary

Status
ACTIVE

Credential Number
PHMF.FX.60798613

Effective Date
10/01/2023

Expiration Date
09/30/2024

Bond Continuation

CONTINUATION CERTIFICATE

To be attached to and form part of Pharmaceutical Wholesaler Surety Bond

Bond Number: 57BSBIA4433

Bond Amount: $25,000.00

On behalf of Principal: Seagen Inc.

Issued by Surety: Hartford Fire Insurance Company

In favor of Obligee: State of Nevada

Bond Effective Date: February 1, 2020

The Surety hereby certifies that this Bond is continued in full force and effect subject to all covenants and conditions of said Bond for the period **February 1, 2024 to February 1, 2025**. Said Bond has been continued in force upon the express condition that the full extent of the Surety's liability under said Bond, and this and all continuations hereof, for any loss or series of losses occurring during the entire time the Surety remains on said Bond, shall in no event exceed the penal sum of the Bond.

IN WITNESS WHEREOF the Surety has caused this instrument to be duly signed, sealed and

Dated as of the 15th day of December, 2023.

Hartford Fire Insurance Company

By: Valerie Takeuchi
Valerie Takeuchi, Attorney-in-Fact

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: WOODRUFF SAWYER & COMPANY
Agency Code: 57-554795

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [X] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [X] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut, (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint, ***up to the amount of*** Unlimited :

Nerissa S. Bartolome, Joan DeLuca, Patrick R Diebel, Lucy M. Dunham, Andrew S. Holloway, Kelly Holtemann, Christopher M. Howell, Thomas E. Hughes, Mark M. Munekawa, Zachary V. Overbay, Christina Parsons, Rossio Polio, Karen Rhodes, Yvonne Roncagliolo, Charles R. Shoemaker, Valerie Takeuchi of SAN FRANCISCO, California

their true and lawful Attorney(s)-in-Fact, each in their separate capacity if more than one is named above, to sign its name as surety(ies) only as delineated above by ☒, and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of December 15, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Seagen Inc.

Pharmacy/Wholesaler License # (if applicable) WH03245

Physical Address 3450 Monte Villa Parkway

City Bothell State WA Zip 98021

Mailing Address (if different from physical address) c/o State License Servicing 1751 State Route 17A, Suite 3

City Florida State NY Zip 10921

Telephone (845) 544-2482 Website www.seagen.com

Licensing Company Email SGN@slsny.com

Section 2: Personal Information

First Ryan Middle Ken Last Takeya

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN _____ Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Lynnwood State WA Zip 98036

Telephone [redacted] Email rtakeya@seagen.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Washington		09/87 - 03/93	
Address	City	State	Zip
1410 NE Campus Pkwy	Seattle	WA	98195
Diploma/Degree obtained, if any			
Bachelor of Arts, Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Mid-Pacific Institute		1982 - 1986	
Address	City	State	Zip
2445 Kaala Street	Honolulu	HI	96822
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/17 - present	[redacted]	Lynnwood	WA	98036
05/04 - 12/17	[redacted]	Lynnwood	WA	98036
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Seagen Inc.			01/2019-Present	
Business Address		**City**	**State**	**Zip**
3450 Monte Villa Parkway		Bothell	WA	98021
Phone	**Title**		**Number of Employed Hours**	
(425) 686-6831	Sr. Director, Manufacturing, Site Head		~ 10,227 hrs	
Description of Duties				
Responsible for site operations; Lead the manufacturing, supply chain, materials management operations for successful execution on clinical and commercial production campaigns. Engage with corporate Quality colleagues to ensure the site operates within corporate compliance with corporate policies and expectations. Work with Product Supply to ensure production schedule meets product supply requirements. Coordinate and engage with stakeholders to ensure the site delivers most value for Seagen				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Ryan Ken Takeya **, certify that as the designated representative for**

Seagen Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RKT I am at least 21 years of age;
3. RKT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RKT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RKT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RKT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RKT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ryan Ken Takeya

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

14 DEC 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Ken Takeya

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 14 DEC 2023

Please have this section completed in the presence of a Notary Public.

State of WASHINGTON, ss. County of SNOHOMISH

I, RYAN KEN TAKEYA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — Ryan Ken Takeya — **Date**: 14 DEC 2023

Subscribed and Sworn to before me this 14 day of December 2023.

Tammy Funk

Notary Public Signature

TAMMY FUNK
Notary Public
State of Washington
Commission # 159243
My Comm. Expires Feb 6, 2028

(Seal)

Employee Name
Anish Sudra
Stacy Clarke
Jeffrey Cooter
Chris Sarver
Kenneth Daugherty
Marina Vasvary
Denise Tanaka Fonseca
Gerard Ranches
Sadi Espinoza
DHannie Cogdell
Jared Yarnish
Dinesh kumar Makarla
Jason Hiner
Tyler Brown
Stacy Tam
Ian Silva
Miguel Alvarez
Shelby Keeley
Matthew Lopez
Joshua Nealey
Brad Lichtblau
Christopher Croson
Jonathan Senasack
Ali Kahiye
Robert Pruszynski
Brian Bush
Laura Oltman
Bjorn Bjorkman
Harold Wenz
John Cetin
Nicole Buhl
Nicholas Markham
Steven Simpson
Christopher Tapper
Todd Wilkie
Donald Thompson
George Alarva
Jesse Otti
Cory Sauer
Maria Rodriguez
Karen Lynch
Matthew Wyszogrodzki
Robert Dedinsky
Ashley Miyano
Scott Hoover
Oscar Lopez
Lesley Darsnek

Tatsiana Kudrytskaya
Paul Phin
Jeffrey Woods
Christopher Schnoor
Randy Rhoades
Michael Horner
Anthony Miller
Shen-Wei Shaw
Paul Driskill
Earl Campbell
Marie Collins
Kristoffer Callo
Brian Chang
Jessica Vaughan
Michael Bauman
Jose Mendiola
Timothy Michnick
Alice Greisch
Ryan Takeya
Lisa Musil
Sara LaCourse
Christopher Green
Laura Cimolino
Benjamin Balansay
Ami Davis
Magdalena Janson
Mara Rolsky
Justin Gerard
Phoebe Ampo
Daniel Matheson
Inne Leung
Marelis Acevedo
Mandeep Hassam
Antonia Heay Stewart
Jonathan Rudd
Megan Long
Katie Tran
Skyler Siebers
Roslyn Whitehill
Madeline Smith
Uyen Ngo
Hope Tranberg
Michael McGrath
Mitchell Goff
Michael Ledesma
James Daigneault
Wildelys Ramos Cintron
Trung Duong

Rachel George
Meagan Pilkerton
Candice Billups
Jesse Hankins
Jasper Remedio
Karen Truong
Tristan Twilligear
Ajla Kovac
Chikodinaka Ezeokeke

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located? New York	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Time-Cap Laboratories, Inc

Physical Address: 235 Pinelawn Road

City: Melville State: NY Zip: 11747

Mailing Address (if different from physical address): 7 Michael Avenue

City: Farmingdale State: NY Zip: 11735

Telephone: 631-753-9090 Website: www.timecaplabs.com

Name of Designated Representative (DR): ANM Khandaker

Licensing Company Email: akhandaker@timecaplabs.com DR Email: akhandaker@timecaplabs.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: OTC, Rx, dietary supplements	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/22/23
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Time-Cap Laboratories, Inc.
Address: 7 Michael Avenue City: Farmingdale State: NY Zip: 11735
Name: Marksans Pharma ~~Inc~~ Ltd.
Address: Opp. Gundecha Symphony City: Veera Desai Ext. Rd State: Mumbai Zip: 400053
Name: Oshiwara Andheri (w)
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

N/A

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): Marksans Pharma Inc.
Corporation/Organization Name: Time-Cap Laboratories, Inc.
Mailing Address: 7 Michael Avenue
City: Farmingdale State: NY Zip: 11735
Telephone: 631-753-9090 Email: akhandalkar@timecaplabs.com
Contact Person Name: Anil Khandalkar

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

N/A

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Time-Cap Laboratories, Inc

Facility Name

Ann Khandker

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/21/2023

Date

Board Use Only	Date Received: 12/13/23	Amount: $1000 - check 0576061

	NDC/NHRIC Labeler	Firm Name
354	82185	Vein and Wellness Group, LLC
355	57707	Pound International Corp.
356	80782	The Wonderful Group L L C
357	54414	Dermatone Labs LLC
358	52015	Merck Sharp & Dohme LLC
359	69876	Almark Products, Inc.
360	37662	Hahnemann Laboratories, Inc.
361	72326	YOUNG PS ACQUISITION, LLC
362	73379	MACSEN DRUGS
363	49483	Time Cap Laboratories, Inc.
364	83061	McF Holdings LLC
365	72559	Little Pharma, Inc.
366	82814	Magnifica Inc.
367	69951	Prevention Health Sciences Inc.
368	62080	Dasan E&T Co., Ltd.
369	64906	Family Medical Equipment & Supply
370	67365	Camelot Healthcare Management, Inc. dba Suncare Respiratory Services
371	54108	derma e
372	72014	H.B.D. D.I.S.T. INC.
373	49252	Inventia Healthcare Limited

verified
M.H 1/24/24

Time-Cap Labs, Inc.

Parent Company: Marksans Pharma Inc. 100% ownership

Corporate Officers:

Mark Saldanda- Chief Executive Officers, Managing Director

[redacted]

James Carroll- Chief Financial Officer

[redacted]

7 Michael Avenue, Farmingdale NY 11735/ Tel: (631) 753-9090 Fax (631)-753-2220
www.timecaplabs.com

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, ROBERT J. RODRIGUEZ, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	TIME-CAP LABORATORIES, INC.
DOS ID Number:	587358
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	10/15/1979
Statement Status:	CURRENT
Statement Due Date:	10/31/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on December 06, 2023 at 12:18 P.M.

ROBERT J. RODRIGUEZ, Secretary of State

Brendan C. Hughes

By Brendan C. Hughes
Executive Deputy Secretary of State

Authentication Number: 100004786877 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
ANM KHANDAKER

THIS IS TO CERTIFY

TIME-CAP LABORATORIES, INC.
235 PINELAWN RD
MELVILLE, NY 11747

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE THIRTEENTH DAY OF OCTOBER, 2023.
THIS CERTIFICATE EXPIRES ON THE THIRTIETH DAY OF SEPTEMBER, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
040536

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

CHUBB

Chubb Surety
436 Walnut St, WA10H
Philadelphia, PA 19106-3703
Karen.Brandt@chubb.com

VIGILANT INSURANCE COMPANY

RIDER to be attached to and form a part of Bond #8253-04-63 on behalf of Time-Cap Labs Inc. as Principal, and VIGILANT INSURANCE COMPANY, as Surety, and in favor of Nevada State Board of Pharmacy, as Obligee.

WHEREAS, when this bond was originally executed, VIGILANT INSURANCE COMPANY was named as Surety, and WHEREAS, it is now desired that the bond be amended to reflect the principal's warehouse change of location.

NOW, THEREFORE, the Surety hereby states the address of the Principal's warehouse is as follows:

235 Pinelawn Rd
Melville, NY 11747

Nothing herein contained shall be held to vary, alter, waive or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, except as herein expressly modified.

Signed, sealed and dated this 29th day of November 2023.

Vigilant Insurance Company

By: Karen Brandt
Karen Brandt, Attorney-in-Fact

Reference: K15341750

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY,** an Indiana corporation, **VIGILANT INSURANCE COMPANY,** a New York corporation, **PACIFIC INDEMNITY COMPANY,** a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Donna Barchman, Frances Bonner, Karen Brandt, Sharon Dean, Barbara Duggan, Rashidah Hasan, Craig Gortner, Rupert Swindells and Lindsay Ward of Philadelphia, Pennsylvania

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this 4th day of **January, 2022.**

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Steven M. Haney

Stephen M. Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this 4th day of **January, 2022,** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316665
Commission Expires July 16, 2024

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this 29th day of November 2023.

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Time-Cap Laboratories, Inc

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 235 Pinelawn Road

City Melville State NY Zip 11747

Mailing Address (if different from physical address) 7 Michael Avenue

City Farmingdale State NY Zip 11735

Telephone 631-753-9090 Website www.timecaplabs.com

Licensing Company Email akhandaker@timecaplabs.com

Section 2: Personal Information

First ANM Middle MUSTAFA Last Khandaker

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Farmingdale State NY Zip 11735

Telephone 631-753-9090 Email akhandaker@timecaplabs.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Long Island University		From - To (MM/YY – MM/YY): 1995 – 2000	
Address: 1 University Plaza	City: Brooklyn	State: NY	Zip: 11201
Diploma/Degree obtained, if any: Master of Science (MS) Pharmaceutical Admin			
School Name: Jahangir Nagar University		From - To (MM/YY – MM/YY): 1981 – 1986	
Address: Saver, Bangladesh	City: Saver	State: Bangladesh	Zip:
Diploma/Degree obtained, if any: BS & MS			
School Name: Chandpur Govt College		From - To (MM/YY – MM/YY): 1974 – 1977	
Address: Chandpur,	City: Chandpur	State: Bangladesh	Zip:
Diploma/Degree obtained, if any: Higher Secondary School Certificate			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
June 9, 2009	[redacted]	Jamaica	NY	11432
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Time-Cap Laboratories, Inc			From - To (MM/YY – MM/YY): 04/19 - Present
Business Address: 7 Michael Avenue	City: Farmingdale	State: NY	Zip: 11735
Phone: 631-753-4090	Title: Director of QA	Number of Employed Hours: 40	
Description of Duties: See attached Resume			

Business Name: American Health Formulations, Inc			From - To (MM/YY – MM/YY): 11/18 - 4/19
Business Address: Hauppauge	City:	State: NY	Zip:
Phone	Title: Director of QA	Number of Employed Hours: 40	
Description of Duties: See attached Resume			

Business Name: Altaire Pharmaceutical Inc			From - To (MM/YY – MM/YY): 07/18 - 4/18
Business Address:	City: Riverhead	State: NY	Zip:
Phone	Title: RA Profect Manager	Number of Employed Hours: 40	
Description of Duties: See attached Resume			

Business Name: Spirit Pharmaceuticals			From - To (MM/YY – MM/YY): 05/16 - 06/18
Business Address:	City: Ronkonkoma	State: NY	Zip:
Phone	Title: Director QA/RA	Number of Employed Hours: 40	
Description of Duties: See attached Resume			

Business Name: Polysen Pharmaceuticals, Inc.			From - To (MM/YY – MM/YY): 01/16 - 08/16
Business Address:	City: Edgewood	State: NY	Zip:
Phone	Title: Director QA/RA	Number of Employed Hours: 40	
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Contract Pharmacal			10/10 - 03/14
Business Address	City	State	Zip
	Hauppauge	NY	
Phone	Title	Number of Employed Hours	
	Manager RA	40	
Description of Duties			
See attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Contract Pharacal			08/08 - 10/10
Business Address	City	State	Zip
	Hauppauge	NY	
Phone	Title	Number of Employed Hours	
	Director of QA	40	
Description of Duties			
See attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Forest Labs, Inc			01/07 - 08/08
Business Address	City	State	Zip
		NY	
Phone	Title	Number of Employed Hours	
	QA Document Control Manager	40	
Description of Duties			
See attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Forest Labs, Inc.			02/95 - 12/06
Business Address	City	State	Zip
		NY	
Phone	Title	Number of Employed Hours	
	Supervisor of QA	40	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Forest Labs, Inc			03/93 - 02/95
Business Address	City	State	Zip
		NY	
Phone	Title	Number of Employed Hours	
	QA Associate	40	
Description of Duties			
See attached Resume			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 10. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

S Kendall

Original Signature (electronic, copies or stamps not accepted)

11/21/2023

Date

I, ANM Khandaker, **certify that as the designated representative for** Time-Cap Laboratories, Inc 235 Pinelawn Rd, Melville NY 11747, **that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Anm Khandaker
Print Name (First, Last)

Khandaker
Original Signature (electronic, copies or stamps not accepted)

11/21/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anm Khandaker

Print Name (First, Last)

A Khadak

Original Signature (electronic, copies or stamps not accepted)

11/27/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Suffolk

I, Anm Khandaker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

A Khadak

Original Signature

11/27/23

Date

Subscribed and Sworn to before me this 27 day of November 2023

Esther Torres

Notary Public Signature

ESTHER TORRES
Notary Public - State of New York
No. 01TO6145033
Qualified in Nassau County
My Commission Expires May 01, 2026

(Seal)

Anm Khandaker 0840

Email: [redacted]

CAREER PROFILE & ACHIEVMENT

Results oriented professional with skills in quality, compliance, regulatory affairs, and cGMP training fields. Have extensive experience in leading & guiding the team involved in the initial set up of cGMP systems & controls for newly built companies in the recent years. Excellent academic & pharmaceutical regulatory background and project management skills. Dependable leadership, communication, organizational, and motivational skills. Demonstrated outstanding leadership in the teams involved in revamping the quality systems, controls and salvaging companies from FDA 483 & warning letters and other regulatory burdens.

CAREER OVERVIEW

DIRECTOR OF QA, Time-Cap Labs, Inc., Farmingdale, NY 04/2019 - to Present

- Planning, developing, and coordinating the activities of the QA/RA/QC departments and assisting COO to achieve production and other company objectives.
- Leading the QA, RA, & QC units to establish and implement the initial set up of GMP systems & controls for compliance with FDA requirements and 3rd party certification.
- Planning & implementation of the facility, equipment, and process qualifications activities.
- Develop, review & approval of policies, procedures, protocols, report, BMRs, BPRs, & labeling, etc. as required for compliance with all regulatory requirements & marketing requirements.
- Manage the day-to-day compliance of the facility, operations and oversee all functions related to manufacturing, packaging, document control, SOPs, change control, internal audits and vendor qualification.
- Review client Quality Control requirements and ensure that Quality Control documentation for the project meets contractual requirements.
- Responsible for licensing, registration, renewal and certification by appropriate regulatory agencies and certification bodies.
- Liaison with the FDA and customers on all technical matters like product recall, complaints and hosting the FDA & other regulatory audits.
- Handling of product complaints with documentation, investigation, and response to customers accordingly.
- Responsible for approving or rejecting all procedures or specifications impacting identity, strength, quality, and/or purity of materials and products manufactured and packaged at AHF.
- Responsible for review and approval or rejection of incoming components, packaging, and labeling materials for use in the manufacturing and packaging.
- Ensure timely & adequate QA/QC coverage in the manufacturing, packaging, testing, and release of products for distribution.
- Train & groom personnel on the cGMP, safety, HACCP, specific job functions & team building in order to meet company objectives.

DIRECTOR OF QA & RA, American Health Formulations, Inc., Hauppauge, NY 11/2018 - to April 2019

- Planning, developing, and coordinating the activities of the QA/RA/QC departments and assisting COO to achieve production and other company objectives.
- Leading the QA, RA, & QC units to establish and implement the initial set up of GMP systems & controls for compliance with FDA requirements and 3rd party certification.
- Planning & implementation of the facility, equipment, and process qualifications activities.
- Develop, review & approval of policies, procedures, protocols, report, BMRs, BPRs, & labeling, etc. as required for compliance with all regulatory requirements & marketing requirements.

- Manage the day-to-day compliance of the facility, operations and oversee all functions related to manufacturing, packaging, document control, SOPs, change control, internal audits and vendor qualification.
- Review client Quality Control requirements and ensure that Quality Control documentation for the project meets contractual requirements.
- Responsible for licensing, registration, renewal and certification by appropriate regulatory agencies and certification bodies.
- Liaison with the FDA and customers on all technical matters like product recall, complaints and hosting the FDA & other regulatory audits.
- Handling of product complaints with documentation, investigation, and response to customers accordingly.
- Responsible for approving or rejecting all procedures or specifications impacting identity, strength, quality, and/or purity of materials and products manufactured and packaged at AHF.
- Responsible for review and approval or rejection of incoming components, packaging, and labeling materials for use in the manufacturing and packaging.
- Ensure timely & adequate QA/QC coverage in the manufacturing, packaging, testing, and release of products for distribution.
- Train & groom personnel on the cGMP, safety, HACCP, specific job functions & team building in order to meet company objectives.

***REGULATORY AFFAIRS* PROJECT MANAGER, Altaire Pharmaceuticals, Inc. Riverhead, NY** 07/2018 – 11/2018

- Assisted General Counsel in the development and planning of regulatory strategies and led the implementation of those strategies to deliver agreed product registration milestones to support the business in a timely and effective manner.
- Independently performed and managed day-to-day product registration operations and ensured timely completion of the registration tasks assigned, in compliance with local applicable laws, regulations, guidelines, and policies and SOPs.
- Drafted product registration strategy plan for review and approval.
- Compiled registration eCTD dossier and prepare other regulatory documents and ensured timely regulatory submission upon review and approval by General Counsel.
- Coordinated internal departments in product registration process.
- Communicated with regulatory agencies/institutes on product registration.
- Timely /closely monitored regulations and reviewed processes for ensuring the data presented fully represented what is practically required and the constantly changing regulations to be followed.
- Met and accelerated Regulatory milestones.
- Properly maintained all regulatory documentation
- Other projects assigned by General Counsel.

DIRECTOR, QA&RA, Spirit Pharmaceuticals LLC, Ronkonkoma, NY *09/2016 – 06/2018*

- Lead the development, implementation, and maintenance of the company's quality and regulatory compliance management systems & operational strategies in alignment with business objectives and capacity in compliance with cGMPs, regulatory agencies and corporate expectations.
- Streamlined process for waste reduction & increase productivity.
- Provided the leadership and guidance on taking quality decisions poised with the business requirements in times of need.
- Involved in planning, developing, and coordinating the activities of the QA/RA department.
- Directed and managed the QA/RA personnel to develop quality policy, procedures/protocols/documents, etc. and prioritized work flow to maximize efficiency.
- Assured facility, equipment & process qualification (IQ, OQ & PQ, temperature mapping, etc.).
- Managed & guided the vendor/supplier qualification program.
- Daily communication & coordination with the vendors/suppliers/distributors/retailers (packaging, labeling, testing & bulk drug products) located in the USA, China, & India.
- Routinely monitored/scheduled third party GMP & social audits (UL, InterTek, Bureau Veritas, NSF, etc.) of supplier facilities located oversees and guided them for preparation of an adequate & compliant response.

- Hosted successful FDA & other regulatory & 3rd party audits at Spirit and prepared responses appropriately.
- Communicated with the FDA & state agencies on various regulatory issues.
- Handled & coordinated product recall activities efficiently.
- Reviewed & approved SOPs, Protocols, reports, BPR/controlled documents, etc. and any amendments to the established procedures.
- Ensured that the procedures specified are followed, assessed and documented the impact of any deviations from the established procedures and to devise appropriate corrective action when necessary; acknowledged deviations from BPRs, SOPs, & protocols etc.
- Ensured timely completion & documentation of all required investigation reports for OOS, deviations, as well as product market complaints etc. at firm & to coordinate with all applicable departments regarding them.
- Handled & ensured investigation & reporting of product complaints, returned goods, OOS, Deviation & Incidents in a timely manner in collaboration & coordination with Spirit Operations & manufacturers/suppliers.
- Ensured that all QA/RA department personnel are well trained to perform their jobs effectively and other administrative functions to ensure an efficient operation that are cost effective & well integrated.
- Prepared, reviewed, & approved regulatory, compliance, CMC documents & labeling/artworks for FDA registration, drug listing & new marketing opportunities.
- Guided new business partners on the regulatory requirements for marketing drugs, dietary supplements, and medical device marketing registration & listing requirements.
- Fostered team environment and facilitate the building of positive, productive relationships for achieving company goals.
- Conducts QA internal audits in order to identify possible gaps & pitfalls for compliance & continuous improvement. Also, conducts periodic reviews of the products & processes to ensure & meet cGMP & OSHA requirements via conducting QRB meeting.
- Assured compliance with all applicable local, state & federal regulations, quality & regulatory standards & other applicable customer's requirements.
- Performed other projects as need by the corporate management.

DIRECTOR, QA & RA, PolyGen Pharmaceuticals, Inc., Edgewood, NY *01/02/16 – 08/ 2016*
ASSOCIATE DIRECTOR, QA& RA, PolyGen Pharmaceutical, LLC., *04/09/14 – 12/2015*

- Involved in planning, budgeting, and coordinating the activities of QA/RA departments. Managed the QA/RA groups to establish and maintain the quality systems & controls, policies, and procedures in order to comply with the cGMP & other local, state, & federal regulations.
- Planned & executed regulatory strategy for licensing, registration and regulatory submissions for ANDAs.
- Coordinated the compilation, review, and submission process for ANDA's, subsequent amendments, including SPL/PLR (labeling), and related CR letters & responses, all interactions and communications with the FDA from product inception to approval, including regulatory support during Pre-Approval Inspections for assigned projects.
- Reviewed and approved SOPs, specifications, protocols, reports, BMRs/BPRs and other GMP documents for accuracy, completeness and compliance.
- Ensured procedures are followed, assessed, and documented the impact of any deviations from the established procedures and took appropriate corrective action based on routine inspection, review, and audits.
- Ensured timely completion & documentation of activities related to CC, OOS, OOT, deviations, product complaints, etc. and related CAPA activities on a timely basis.
- Ensured cGMP, OSHA and other regulatory trainings are conducted for all related personnel in a timely fashion.
- Conducted QA internal audits to identify risks and gaps in the quality systems & controls.
- Ensured OSHA, EPA, and other agency regulations are enforced in the company.
- Coordinated all licensing, registration and reporting activities related to procurement, storage, handling and distribution of controlled drug substances (DEA). Routine inspection & review of BPRs, logs, inventories & DEA cage & bolts.
- Ensured compliance with all applicable local, state & federal regulations, quality & regulatory standards & other applicable customer requirements.
- Other projects as assigned by the corporate management.

MANAGER OF REGULATORY AFFAIRS, Contract Pharmacal Corporation, Hauppauge, NY 10/2010 – 03/2014

- Managed states & federal licensing, certification, and registration activities such as state board of pharmacies, FDA/FEI registration, FSC, CPP, Medical device, USDA - import/export, organic certifications & maintaining program, etc.
- DEA registration, renewals and worked with operations for procurements, storage, inventory, distribution & destruction of controlled substances & listed chemicals. Prepared & submitted ARCOS & yearend reports. Routine inspection & review of logs, inventories & DEA cage & bolts.
- Prepared, reviewed, and approved product labeling and printed components (labeling, medication guide, inserts & IFCs) for compliance with 21 CFR parts 101 & 201 as well as customer requirements.
- Managed supplier qualification programs.
- Prepared, reviewed, and approved the annual product review (APR) reports and process validation reports using statistical charts and graphs.
- Coordinated customer and regulatory agency audits.
- Investigated and responded to customer queries on product formulation, packaging, allergens and drug/supplemental/nutritional facts.
- Prepared, reviewed, and approved CMC documentation and Dossiers for local and international product registration and submissions.

DIRECTOR OF QUALITY ASSURANCE, Contract Pharmacal Corporation, Hauppauge, NY 08/2008 – 10/2010

- Developed and managed SOPs, protocols, quality agreements and other related documentation systems.
- Initiated, reviewed/managed documents and reports related to deviation and OOS investigation, product complaints, change controls and related CAPA activities.
- Reviewed and approved formulation records and finished product specification and ingredient listings.
- Developed and managed corporate training matrix for new employees in light of cGMP, safety and other related FDA, OSHA & DEA regulations.
- Performed quality audits on CMC documents of ANDA & other marketing registration with emphasis on data verification, source document accuracy, and clear messaging within and between documents.
- Ensured all quality-based deliverables complied with regulatory and quality policies and procedures and timelines are met and observations are corrected.
- Conducted internal & external audits.

QA DOCUMENT CONTROL MANAGER, Forest Laboratories, Inc. **(Currently Allergan)**, *NY* 01/2007 – 08/2008

- Managed SOPs, master batch records, deviation/investigation reports, test methods, specifications, protocols, reports & forms using EDMS.
- Conducted complaint investigation, prepared APRs, and managed change controls and CAPA activities.

SUPERVISOR OF QA, Forest Laboratories, Inc. **(Currently Allergan)**, *NY* 02/1995 – 12/2006

- Supervised QA Associates & Technicians for accomplishing daily QA activities in the manufacturing and packaging operations & ensured timely inspection, sampling, line clearance, review and release of finished product batches for packaging and distribution including CS.
- Reviewed and approved IND/stability/bio batches for R&D clinical packaging and regulatory submissions.
- Assisted regulatory group for compilation of CMC data & assisted in the preparation of site master validation plan, technical agreement and site DMF.
- Prepared, reviewed, and approved process & cleaning validation protocols and reports.
- Involved in the IQ, OQ & PQ of the newly procured manufacturing equipment, facilities, & QA inspection devices. Audited equipment calibration, qualification, & preventive maintenance programs.
- Prepared, reviewed, and revised SOPs. Conducted deviation investigation, customer product complaint investigations using the TrackWise Quality Management software.
- Assisted head of QA in registration and reporting activities related to procurement, storage, handling and distribution of controlled drug substances. Routine inspection & review of related BPRs, logs, inventories, DEA cage & bolts.

- Initiated, coordinated, and documented change control and CAPA activities.
- Conducted internal and external/vendor audits for compliance with the cGMPs.
- Involved in the teams established for FDA, PAI, EIR inspections, product recalls, and field alert activities.
- Prepared, reviewed, and approved the annual product review reports using statgrphics software.
- Conducted cGMP training for QA/QC, PR&D and Production personnel.
- Coordination of online GMP training programs sponsored by FDA & Eduneering, Inc.
- Represented QA department in the cross-functional meetings and projects.

QUALITY ASSURANCE ASSOCIATE, Forest Laboratories, Inc.* (Currently Allergan), *NY 03/1993 – 02/1995

Inspected and sampled incoming raw materials for QC testing. Performed QA line clearance & in-process inspection of manufacturing operation. Performed USP & Potable water systems, Compressed air systems, and environmental air sampling. Monitoring temperature/humidity in the manufacturing & stability rooms. Calibration of temp/humidity recorders, thickness gauges, hardness testers, and calipers. Monitored air-pressure differential in the manufacturing rooms. Reviewed and released batch records. Reviewed and released the IND/NDA/ANDA batches clinical packaging and regulatory submissions. Prepared & revised SOPs, deviation investigation reports and other procedures for compliance with cGMPs.

QUALITY ASSURANCE ASSOCIATE, Interpharm* (Currently Amneal), *Plainview, NY 08/1990 – 03/1993

Reviewed & released manufacturing batch records. Conducted line clearances prior to start of manufacturing & packaging operations. Reviewed executed batch records, packaging worksheets for accuracy and completeness, and released for distribution. Sampled raw materials and packaging components for QC testing and release. Conducted physical analysis of the in-process blends/granules and finished products using moisture analyzer, friabilator, disintegration apparatus, and bulk/tap density analyzer. Archived and maintained executed manufacturing batch records and QC analytical reports. Maintained stability and retained samples.

EDUCATION & TRAINING

MS – Drug Regulatory Affairs, Long Island University, New York.
BS & MS - Government and Administration, Jahangir Nager University, Bangladesh.
Minor degree course works: Economics, Chemistry, Biology, Physics, Geography, & Statistics.

Attended training courses on Validation, Change control, stability testing, GMP for bulk pharmaceutical, Writing validation protocols, application of GMPs to Microbiological Laboratories, Risk Management, FDA 483, Preparing FDA PAI/EIR inspection, Drug Recalls, Computer system validation, Electronic Records & Signatures, Evaluating Raw Materials for the Development of Pharmaceutical Products, Advance Practices in Pharmaceutical Tableting, SPC, Validation by Design, Quality Management Skills organized by University of Wisconsin, FDA/Eduneering, PDA, PTI, LP Resources & GMP Institute.

Trained on EDMS, SPC, SAP, TrackWise, AlphaLan, Microsoft Word/Excel/Outlook/PowerPoint, etc.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Reg. No. : 0845 05
Sr. No. : 4370 | 23
DATE : 7 | 12 | 23

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Time-Cap Laboratories, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 235 Pinelawn Road

City: Melville State: NY Zip: 11747

Mailing Address (if different from physical address): 7 Michael Avenue

City: Farmingdale State: NY Zip: 11735

Telephone: 631-753-9090 Website: www.timecaplabs.com

Licensing Company Email: akhandaker@timecaplabs.com

Section 2: Personal Information

First: Mark Middle: Last: Saldanha

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Farmingdale State: NY Zip: 11735

Telephone: 631-753-9090 Email: mark.s@marksanspharma.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

NOTARY B. C. Yadav Gr Mumbai Maharashtra Regn No 10049 GOVERNMENT OF INDIA

NOTARY BRAJESH C. YADAV Gr Mumbai Regd. No. 10049 GOVT. OF INDIA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Mumbai			From - To (MM/YY – MM/YY): 0846	
Address: Kaliana	City: Mumbai, India		State: MAM	Zip: India
Diploma/Degree obtained, if any: Bachelor of Science				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Jan/15-present	[redacted]	Port Jefferson	NY	11777
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

NOTARY BRAJESH C. YADAV Greater Mumbai Regd. No. 10049 GOVT. OF INDIA

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Marksans Pharma Ltd.			From - To (MM/YY – MM/YY): Present
Business Address: 11th Floor, Grandeur, Opp. Gundecha Symphony, Veera Ext. RD	City: Oshiwara, Andheri	State: Mumbai	Zip: India
Phone: 91.22.4001.2000	Title: CEO		
Description of Duties: CEO/Managing Director			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

NOTARY GOPALDAS C. YADAV Greater Mumbai Regn. No. 49 GOVT. OF INDIA

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

NOTARY BRAJESH C. YADAV Greater Mumbai Regd. No. 10049 GOVT. OF INDIA

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

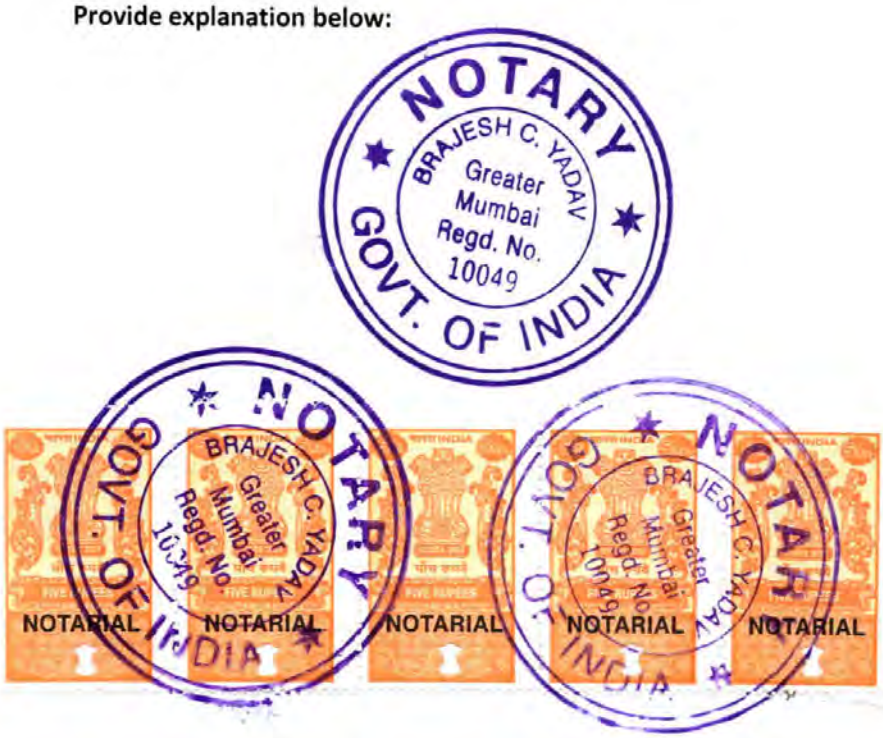
NOTARY
BRAJESH C. YADAV
Greater Mumbai
Regd. No. 10049
GOVT. OF INDIA

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

12/7/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

0691

Mark Saldanha

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/07/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Mark Saldanha, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/07/2023

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

NOTARY
BRAJESH C. YADAV
Greater Mumbai
Regd. No. 10049
GOVT. OF INDIA

BEFORE ME

7/12/23

BRAJESH C. YADAV
ADVOCATE & NOTARY
GOVT. OF INDIA
Flat No. 505, Bldg. No.21-G, Laxmi C.H.S.
Sangharsh Nagar, Chandivali Farm Road,
Anderi (E), Mumbai - 400 072.

(Seal)

Reg. No. :	05
Sr. No. :	4370/23
DATE :	7/12/23

List of employees for Time-Cap Laboratories

Full name	Position	Org	Department
ABREU DE ROSADO, NAYELI A	OPERATOR	600	Packaging
ABREU, FIOR D	OPERATOR	600	Packaging
ABREU, ROBERT	WARE HOUSE ASSOCIATE	800	Shipping and Rec
ACHARJEE, DHIMAN	QA INSPECTOR	501	Quality Assuranc
AKTER, NARGIS	QA INSPECTOR	501	Quality Assuranc
ALEXANDRE, LOUIS D	OPERATOR	600	Packaging
ALLI, MOHAMED S	OPERATOR	401	Tableting
ALVARADO, MAYRA R	OPERATOR	401	Tableting
ALVARENGA, KAROL V	OPERATOR	600	Packaging
ANJANI KUMAR, FNU	CHIEF OPERATING OFFICER	100	V.P. Administrat
ARGUERA, JUAN C	OPERATOR	600	Packaging
ARISTHILDE, ESTHER	MACHINE OPERATOR	600	Packaging
BAEZ, JOSE R	OPERATOR	400	Blending
BAKSH, BIBI S	LEAD OPERATOR	600	Packaging
BALI, VIPIN	STAFF ACCOUNTANT	600	Packaging
BANEGAS GOMEZ, MARIA I	ADMINISTRATIVE ASSISTANT	200	Office Administr
BASNET, SURENDRA B	Maint Tech	700	Maintenance
BEAUZILE, JEAN G	FORK LIFT OPERATOR	800	Shipping and Rec
BELAL, RUSSEL F	QA INSPECTOR	501	Quality Assuranc
BENJAMIN, SHERLY	QA INSPECTOR	501	Quality Assuranc
BHUIYAN, SHAMSUL H	QA INSPECTOR	501	Quality Assuranc
BLAIR, DAVID J	ASST. SUPERVISOR - WH	800	Shipping and Rec
BLENMAN, HUGH D	MACHINE OPERATOR	400	Blending
BOLEY, SHAMEQUA	DOCUMENT CONTROL COORDINATC	501	Quality Assuranc
BOPCHE, ROSHNI K	LEAD - SAFETY	200	Office Administr
BRIDGNANAN, MARLON L	LEAD OPERATOR	301	Pellet Coating
BROGGELWIRTH, KENNETH J	DIR OF IT	200	Office Administr
CAJAS, INGRID L	OPERATOR	600	Packaging
CANALES, DINA	OPERATOR	600	Packaging
CANALES, KARINA M	OPERATOR	600	Packaging
CANALES, SANDRA L	LEAD OPERATOR	600	Packaging
CAPIRAL, CHRISTOPHER N	LEAD OPERATOR	400	Blending
CARDONA, LUCENY	OPERATOR	600	Packaging
CARROLL, JAMES	CHIEF FINANCIAL OFFICER	100	V.P. Administrat
CASTILLO ULLAURI, JENNY S	OPERATOR	600	Packaging
CASTRO, ALEX J	WAREHOUSE MANAGER	800	Shipping and Rec
CASTRO, BRIANN M	ADMINISTRATIVE ASSISTANT	101	Production Admin
CASTRO, JOSEPH A	WARE HOUSE ASSOCIATE	800	Shipping and Rec
CASTRO, MIRIAN R	OPERATOR	600	Packaging
CERCADO, CRISTOBAL C	WARE HOUSE ASSOCIATE	800	Shipping and Rec
CHACON, ROSA	WARE HOUSE ASSOCIATE	800	Shipping and Rec
CHANG, CHIA-WEI	IT Specialist	200	Office Administr
CHERIAN, SUJA R	QA INSPECTOR	501	Quality Assuranc
COBO, FABIAN	WARE HOUSE ASSOCIATE	800	Shipping and Rec

HOSSAIN, MOHAMMED Z	QA INSPECTOR	501 Quality Assuranc
HUAYTA, JULIO C	WAREHOUSE ASSOCIATE	800 Shipping and Rec
HUSSAIN, MUNIR	Electrical Technician	700 Maintenance
JAVED, MARIA K	TRAINEE	500 Laboratory
JOHNSON, DARREN	MATERIAL HANDLER	800 Shipping and Rec
JOHNSON, SHANNON M	WARE HOUSE ASSOCIATE	800 Shipping and Rec
JOSEPH, VARGHESE	MACHINE OPERATOR	401 Tableting
KADAM, PRASHANT J	MANAGER MAINTENANCE	700 Maintenance
KAUR, PURSHINDER	MACHINE OPERATOR	600 Packaging
KAUR, SACHLEEN	CUST SERVICE REPRESENTATIVE	200 Office Administr
KELLYMAN-JOHNSON, MERTELLA	REG AFFAIRS ASSOC	201 Regulatory Affai
KHAN, ASAYAH B	DATA ENTRY CLERK	101 Production Admin
KHANDAKER, ANM M	DIRECTOR OF QA	501 Quality Assuranc
KOTHAPALLY, AMALA	SR. ASSOCIATE - REG. AFFAIRS	201 Regulatory Affai
KRAMPS, KIMBERLY G	ACCT PAYABLE ADMIN	200 Office Administr
KUMAR, MOHIT	WARE HOUSE ASSOCIATE	800 Shipping and Rec
KURUVILLA, TESSY	QA INSPECTOR	501 Quality Assuranc
LESSER, GAYLE I	CONTRACT SPECIALIST	200 Office Administr
LIRA, ROXANNA D	ACCOUNT SPECIALIST	200 Office Administr
LOUIS JEAN, BOURDO	DRIVER	800 Shipping and Rec
MALDONADO, SANTOS S	OPERATOR	400 Blending
MALDONADO, TARYN D	ASSISTANT SUPERVISOR	600 Packaging
MALLINENI, PRAVEENA	CHEMIST	500 Laboratory
MARCOPULOS, FRANK	QA INSPECTOR	501 Quality Assuranc
MARQUEZ, YENY C	OPERATOR	600 Packaging
MARTINEZ, BRANDON J	WARE HOUSE ASSOCIATE	800 Shipping and Rec
MARTINEZ, CARLOS R	DRIVER	800 Shipping and Rec
MARTINEZ, WALTER A	WAREHOUSE ASSOCIATE	800 Shipping and Rec
McDaniels, CHARLES T	WAREHOUSE ASSOCIATE	800 Shipping and Rec
MENDEZ, JHOANNA C	MACHINE OPERATOR	600 Packaging
MOLINA MEJIA, YANNY J	WAREHOUSE ASSOCIATE	800 Shipping and Rec
MONJARAS, VALENTINA A	MACHINE OPERATOR	600 Packaging
MONJARAS-ARGUETA, ANA J	ASSISTANT MANAGER	600 Packaging
MOSCOSO, DANTE M	TRAINEE	600 Packaging
NAYYAR, IRFAN	WARE HOUSE ASSOCIATE	800 Shipping and Rec
NAZEER, BIBI S	MACHINE OPERATOR	401 Tableting
OBANDA, DAUDI	MATERIAL HANDLER	800 Shipping and Rec
OLIVER, PIERRE R	OPERATOR	600 Packaging
ORTEGA, LUZ	WAREHOUSE CLERK	800 Shipping and Rec
PAGAN, JOAN OMAR	FILM COATING SPVR	302 Film Coating
PALOMINO NODARSE, LEONARDO	WAREHOUSE ASSOCIATE	800 Shipping and Rec
PANAMENO, ANA M	OPERATOR	600 Packaging
PASHA, BIBI Z	MACHINE OPERATOR	302 Film Coating
PATEL, ARTIBEN R	CHEMIST	500 Laboratory
PATEL, BRIJESH A	CHEMIST	500 Laboratory
PATEL, KRUTI N	REG AFFAIRS ASSOC	201 Regulatory Affai
PATEL, MANESH C	DIR OF QUALITY CONTROL	500 Laboratory

WELLS, KENNETH	ASST. SUPERVISOR - WH	800 Shipping and Rec
WOLF, KAREN M	A/R SPECIALIST	200 Office Administr
WRAY, OMAR A	Maint Tech	700 Maintenance
XIE, YUFEN	MANAGER - PURCHASE	200 Office Administr
YESUDAS, STELLA	QA INSPECTOR	501 Quality Assuranc
ZACHARIAH, ALEXANDER	PRODUCTION MANAGER	101 Production Admin
ZUNIGA, CARLOS J	MACHINE OPERATOR	600 Packaging

4Q

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ■ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03400	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Vantive US Healthcare LLC

Physical Address: 7511 114th Avenue North

City: Largo State: FL Zip: 33733

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip: 43017

Telephone: (727) 541-6411 Website: www.baxter.com

Name of Designated Representative (DR):

Licensing Company Email: licensure@cardinalhealth.com DR Email: david_wheeler@baxter.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see attached

LaTanya M. Mann

Original Signature (electronic, copies or stamps not accepted)

11/30/2023

Date

Vantive US Healthcare, LLC Disclosures

There are no relevant disciplinary actions taken against the applicant corporation Vantive US Healthcare, LLC ("Vantive US") or the facility related to the license. Vantive US is a subsidiary of Baxter Healthcare Corporation, which in turn is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange with tens of thousands of employees world-wide. For purposes of transparency, we are providing disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation. Additional information regarding specific Vantive US or Baxter Healthcare Corporation facilities (e.g., inspection history) can be found on the FDA website.

State Pharmacy License Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling,

and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities.

Iowa, Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third party logistics provider. Inspectors concluded Baxter (Round Lake, IL) violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor – health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved this matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Officer Disclosure

The Vice President and Secretary of Baxter Healthcare Corporation had a misdemeanor DUI conviction in December 2000, in Austin, Texas.

Vantive US Healthcare LLC

1 Baxter Parkway, Building 6
Deerfield IL
1-800-333-0887

November 28, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV, 89521

RE: Licensing activity related to Baxter Healthcare and the legal separation of its Kidney Care business, resulting in the attached Vantive US Healthcare LLC manufacturer License Application

To whom it may concern

This letter is intended to provide you with supporting background information for the attached wholesaler application for Vantive US Healthcare LLC.

In early 2023, Baxter International Inc. publicly announced the intention to separate its Kidney Care (renal and acute therapies) business into a new, independent, publicly traded company– the name of this new company is Vantive. The final separation is planned for mid-year 2024, subject to customary closing conditions and receipt of regulatory approvals.

A new legal entity, Vantive US Healthcare LLC, has been formed as a first step in the legal separation. Vantive US Healthcare LLC is currently a subsidiary of Baxter Healthcare Corporation, which is a subsidiary of Baxter International, Inc.. Vantive US Healthcare LLC will remain an indirect subsidary of Baxter International, Inc. until the final separation of the two companies mid year 2024. However, prior to that final separation and starting on February 1, 2024, sales for the Kidney Care products will be through Vantive US Healthcare LLC.[1]

Baxter Healthcare Corporation currently sells these theraputic products, which are used in the treament of end stage kidney disease, directly to patients at home. For this reason Baxter Healthcare Corporation is currently licensed in your state as a wholesaler permit # WH03400 The activities of Vantive US Healthcare LLC will be no different than those currently occurring with the existing Baxter Healthcare Corporation wholesaler therefore there should be no distinction between the existing Baxter Healthcare Corporation license and the attached application for Vantive US Healthcare, LLC.

[1] Please note: although the site that is the subject of the attached license application is being transferred from Baxter to Vantive, the FEI number associated with the FDA Establishment Registration of this facility will remain the same on February 1, 2024.

We are providing this notification as we are requesting assistance by the state to ensure issuance of the attached license prior to February 1, 2024 in order to guarantee continuity of product supply to patients. Please contact me if there are any additional questions or concerns.

Sincerely,

LaToyia M. Martin
Manager, Quality Compliance

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Please see attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Baxter Healthcare Corporation

Corporation Name: Vantive US Healthcare LLC

Mailing Address: One Baxter Parkway

City: Deerfield State: IN Zip: 60015

Telephone: 224-948-2000 Email: licensure@cardinalhealth.com

Contact Person Name: Chauna Mason

Date of SEC Registration: 10/19/1931 | SEC Registration Number: 0000010456 | Stock Exchange Symbol: BAX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Vantive US Healthcare LLC

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/30/23

Date

Board Use Only	Date Received: 12/7/23	Amount: $1000 - check 10882398

Section# 3.

Benchmark
56 S. Rockford Dr.
Temple, AZ 85288
1.833.236.2400

Baxter Healthcare SA
2 Woodlands Industrial Park D, Street 2
Singapore, 737778
65.3636855555

Leoch Battery
Unit C, 33/F, TML Tower, No. 3 Hoi
Shing Road, Tsuen Wan, N.T., H.K.
852.2117.0016

Elk Grove Graphics
2451 Lively Blvd.
Elk Grove Village, IL, 60007-6726
651.228.2200

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
BAXTER HEALTHCARE CORPORATION
Business Trade Name:
Medical Products

7511 114TH AVENUE NORTH
LARGO, FL 33773
Registration Number: 1036337
FEI Number*: 1036337
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
BAXTER HEALTHCARE CORPORATION[6]
One Baxter Parkway
Deerfield, IL US 60015
Owner/Operator Number: 1417572[7]

Official Correspondent:
Milena Vicente
One Baxter Parkway
Deerfield, IL 60015
Phone: 224-2218256

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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√valid 12/15/23

Page Last Updated: 11/27/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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U.S. Department of **Health & Human Services**

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CardinalHealth

7511 114th Avenue North
Largo, Florida 33773

Officer Name	Title
Michael A. Cascella, Jr.	Vice President, Tax
Matthew Koller Harbaugh	VP, Finance
Karen L. Leets	Vice President and Treasurer
James William Borzi	SVP, Chief Supply Chain Officer
Ellen K. Bradford	SVP and Corporate Secretary

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Select Year: 2023 Go

The 2023 Florida Statutes

Title XXXIII
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS

Chapter 499
FLORIDA DRUG AND COSMETIC ACT

View Entire Chapter

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or device to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must

notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21; s. 36, ch. 2014-89; s. 10, ch. 2016-212; s. 33, ch. 2017-3; s. 1, ch. 2017-51; s. 8, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 8, ch. 2019-99, amends subsection (1), to read:

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

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DIVISION OF DRUGS, DEVICES AND COSMETICS – FAQS

Drugs, Devices & Cosmetics FAQs

To obtain an interpretation of statute or rule from an agency requires the submission of a Petition for Declaratory Statement that is authorized by Chapter 120, Florida Statutes and an agency cannot provide an informal legal opinion. The responses to the frequently asked questions are not intended to be legal opinions or statements of agency policy and you are strongly encouraged to seek the guidance of a regulatory consultant to assist you regarding the interpretation and application of Florida Statutes and rules.

Definitions:

- "DBPR" or the "department" or refers to the Florida Department of Business and Professional Regulation.
- "DEA" refers to the U.S. Drug Enforcement Administration.
- "ARCOS" refers to the Automation of Reports and Consolidated Orders System operated by DEA.
- "CSR" refers to Florida's state analogue to ARCOS, the Controlled Substance Reporting system.
- "E-FORCSE (https://florida.pmpaware.net/login)" refers to Florida's "Electronic-Florida Online Reporting of Controlled Substances Evaluation", aka the "Prescription Drug Monitoring Program" or "PDMP". For more information visit the E-FORCSE homepage at https://www.floridahealth.gov/statistics-and-data/e-forcse

/index.html (https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html).

— Division of Drugs, Devices and Cosmetics

Does my company need a permit?

DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories:(a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?
Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No
Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a "drug", "device", or "cosmetic"?

Refer to Section 499.003, Florida Statutes: http://www.leg.state.fl.us/statutes /index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections /0499.003.html (http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute& Search_String=&URL=0400-0499/0499/Sections/0499.003.html) Please note that "drug"

Global Risk Management

Baxter

MEMORANDUM OF LIABILITY INSURANCE	Date Sept 1, 2023

This Memorandum is issued as a matter of information only to authorized viewers for their internal use and confers no rights upon any viewer of this Memorandum. This Memorandum does not amend, extend or alter the coverage described below. This Memorandum may only be copied, printed, and distributed by an authorized viewer and may only be used by an authorized viewer for internal use. Any other use, duplication or distribution of this Memorandum without prior written consent of Baxter Risk Management is prohibited. This memorandum does not constitute a contract between authorized viewer and the issuing Insurer(s) or Baxter. Neither the Insured nor the producer shall have the obligation to inform an authorized viewer of any changes to this information. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Memorandum via https://connect.baxter.com/sites/functions/RiskMngmt/Pages/Certificates-of-Insurance.aspx.
The information contained herein is as of the date referred above.

INSURED
Baxter International, Inc. and
All Affiliates, Divisions and Subsidiaries thereof including
Baxter Healthcare Corporation and Hillrom Holdings, Inc.
One Baxter Parkway
Deerfield, IL 60015 USA

INSURER(S) AFFORDING COVERAGE	NAIC#
A: Old Republic Insurance Company	24147
B: Illinois Union Insurance Company	27960
C: Steadfast Insurance Company	26387
D:	
E:	
F:	

COVERAGES

THE POLICIES OF THE INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS MEMORANDUM MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

CO LTR	TYPE OF INSURANCE	POLICY NUMBER	POLICY EFFECTIVE (MM/DD/YYYY)	POLICY EXPIRATION (MM/DD/YYYY)	LIMITS (USD)	
A	**COMMERCIAL GENERAL LIABILITY**	MWZY 57820 23	9/1/2023	9/1/2024	EACH OCCURRENCE	$2,000,000
					DAMAGE TO RENTED PREMISES	$50,000
					MED EXPENSE	$25,000
					PERSONAL & ADV INJURY	$2,000,000
					GENERAL AGGREGATE	$4,000,000
					PRODUCTS - COMP/OP AGG	Excluded
A	**AUTOMOBILE LIABILITY**	MWTB 20158 23	9/1/2023	9/1/2024	COMBINED SINGLE LIMIT	$5,000,000
B	**UMBRELLA LIABILITY**	XEUG27981604 008	9/1/2023	9/1/2024	EACH OCCURRENCE	$3,000,000
					AGGREGATE	$3,000,000
A	**WORKERS COMPENSATION AND EMPLOYER'S LIABILITY** Any Proprietor / Partner / Executive Officer / Member Excluded? **N**	MWC11550216 (All Other States)	9/1/2023	9/1/2024	PER STATUTE	
					E.L. EACH ACCIDENT	$2,000,000
A		MWXS82923 (Excess IL)	9/1/2023	9/1/2024	E.L. DISEASE EA EMPLOYEE	$2,000,000
					E.L. DISEASE POLICY LIMIT	$2,000,000
A	**PRODUCT LIABILITY**	MWZY 31692223	9/1/2023	9/1/2024	EACH CLAIM	$5,000,000
					AGGREGATE	$5,000,000
C	**CYBER LIABILITY** Network and Security	SPR 0142190-06	5/1/2023	5/1/2024	LIMIT	$5,000,000

ADDITIONAL INFORMATION

The Memorandum of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications here to are not authorized.

VANTIVE US HEALTHCARE LLC

POWER OF ATTORNEY

As contemplated by the resolutions adopted by the Board of Directors of Vantive US Healthcare LLC, a Delaware limited liability corporation ("the Corporation"), effective October 20, 2023 ("Resolutions"), a copy of such Resolutions is attached hereto as Exhibit A, the undersigned Matthew Rice, Assistant Secretary, an Authorized Representative of Vantive US Healthcare LLC, hereby delegates to Keegan Chamberlain, Director of Quality Management and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of Vantive US Healthcare LLC.

This power of attorney shall be effective until December 31, 2024 and is subject to revocation by any officer of Vantive US Healthcare LLC at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: October ___, 2023

Vantive US Healthcare LLC

Matthew Rice
Assistant Secretary
Authorized Representative

EXHIBIT A

VANTIVE US HEALTHCARE LLC
MISCELLANEOUS RESOLUTIONS
Adopted October 20, 2023

VANTIVE US HEALTHCARE LLC

WRITTEN CONSENT
OF THE MANAGERS

Effective as of October 20, 2023 ("Effective Date")

THE UNDERSIGNED, being all of the managers (the "Managers") of Vantive US Healthcare LLC, a Delaware limited liability company (the "Company"), do hereby, pursuant to the provisions of Section 18-404 of the Delaware Limited Liability Company Act, approve, adopt, consent to and vote for the following actions and resolutions and each and every action effected thereby:

APPROVAL OF THE FORMATION AND FORMATION ACTIONS

MISCELLANEOUS

RESOLVED, that any Manager or officer of the Company, or such other individuals that the Company shall, by power of attorney or otherwise, determine to be necessary, appropriate or advisable (together, the "Authorized Representatives" and each, an "Authorized Representative"), be and each hereby is authorized, empowered and directed, acting jointly with one or more other Authorized Representatives, to do or cause to be done all things and acts, to negotiate, approve, execute, acknowledge, sign, deliver, file and perform or cause to be negotiated, approved, executed, acknowledged, signed, delivered, filed and performed on behalf of the Company any such agreements, instruments or other documents, make all filings, issue powers of attorney, and otherwise take any further action, which in the judgment of the Authorized Representatives are necessary, appropriate or advisable to consummate the foregoing resolutions and perform its obligations thereunder and otherwise to carry out and comply with the intent and purposes of the resolutions herein;

FURTHER RESOLVED, that all of the past acts and transactions of any Authorized Representative (or other representative or agent of the Company), including, but not limited to, preparation, execution, deliveries and filings of agreements, instruments, certificates and other documents in the name of and on behalf of the Company or any of its affiliates, and all fees and expenses (including taxes) incurred or paid by any Authorized Representative (or other representative or agent of the Company) having been deemed necessary, proper or advisable to carry out the intent and effectuate the purposes hereof, prior to the execution of these resolutions, taken in good faith in the name and on behalf of the Company or any of its affiliates pursuant to and consistent with the resolutions contained herein, be and hereby are consented to, adopted, authorized, approved, confirmed and ratified in all respects; and

FURTHER RESOLVED, that these resolutions may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts

together shall constitute one and the same instrument.

(Signature page follows)

IN WITNESS WHEREOF, the undersigned have duly executed this Written Consent effective as of the Effective Date.

Christopher Toth, Manager

David S. Rosenbloom, Manager

Joel T. Grade, Manager

412992826

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Baxter Healthcare Corporation — MDEG License # (if applicable): MP00799

Physical Address: 7511 114th Avenue North

City: Largo — State: FL — Zip: 33773

Mailing Address (if different from physical address): 7000 Cardinal Pl. Attn: QRA - Facility Licensing

City: Dublin — State: OH — Zip: 43017

Telephone: 614-553-3420 — Website: www.baxter.com

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: David — Middle: Kenneth — Last: Wheeler

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Largo — State: FL — Zip: 33773

Telephone: [redacted] — Email: licensure@cardinalhealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Elmira College		1982 to 1984	
Address	City	State	Zip
One Park Place	Elmira	N Y	14901
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Corning Community College		1980 to 1982	
Address	City	State	Zip
1 Academic Drive	Corning	NY	14830
Diploma/Degree obtained, if any			
Associate of Science Degree			

School Name		From - To (MM/YY – MM/YY)	
Corning-Painted Post East High School		1972 to 1976	
Address	City	State	Zip
201 Cantigny St.	Corning	N Y	14830
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2013 to Present	[redacted]	N Redington Bch	FL	33708
2005 to 2013		Columbia	SC	29229

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY - MM/YY)	
Baxter Healthcare Corporation			10/2017 to Present	
Business Address		**City**	**State**	**Zip**
7511 114th Ave		Largo	FL	33773
Phone	**Title**		**Number of Employed Hours**	
727-548-2123	Associate Director, Technical Services		10,400	
Description of Duties				
Lead executive at the Largo facility responsible for the servicing of Baxter Medcial Devices				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✔	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*: See attached

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/02/2023
Date

I, David Kenneth Wheeler, certify that as the MDEG Administrator for

Baxter Healthcare Largo Facility,

that I (initial that you have read and meet the following requirements):

1. DKW Have a high school diploma or its equivalent;
2. DKW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DKW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DKW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Wheeler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/02/2023

Date

Board Use Only	Date Received: 3-7-23 (orig) Scanned & Rec'd -mP00799

Baxter Healthcare Corporation Disclosures

The corporate owner of the applicant facility is Baxter Healthcare Corporation. Accordingly, as part of this application we have provided disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation. We cannot answer application questions with respect to all owners and shareholders, given that Baxter Healthcare Corporation is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange. We also cannot answer with respect to all Baxter Healthcare Corporation employees given the scope of Baxter's US operations.

FDA-related information regarding specific Baxter Healthcare Corporation facilities (e.g., inspection history and enforcement actions) can be found on the FDA website.

State Pharmacy License Disciplinary Actions

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-

corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities.

Iowa, Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third party logistics provider. Inspectors concluded Baxter (Round Lake, IL) violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to

obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

Pending Disciplinary Action

Utah, License # 12435996-1710

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Pending matter, waiting on the order and to pay the fine.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor – health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved this matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred

prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

Employee List

7511 114th Avenue North
Largo, Florida 33773

Officer Name	Title	Company
Michael A. Cascella, Jr.	Vice President, Tax	Vantive US Healthcare LLC
Matthew Koller Harbaugh	VP, Finance	Vantive US Healthcare LLC
Karen L. Leets	Vice President and Treasurer	Vantive US Healthcare LLC
James William Borzi	SVP, Chief Supply Chain Officer	Vantive US Healthcare LLC
Ellen K. Bradford	SVP and Corporate Secretary	Vantive US Healthcare LLC
David Wheeler	Sr. Manager, Plant Lead	Vantive US Healthcare LLC

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 1-4448

Baxter

Baxter International Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	36-0781620
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
One Baxter Parkway, Deerfield, Illinois	60015
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code 224.948.2000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common stock, $1.00 par value	BAX (NYSE)	New York Stock Exchange
		Chicago Stock Exchange
0.4% Global Notes due 2024	BAX 24	New York Stock Exchange
1.3% Global Notes due 2025	BAX 25	New York Stock Exchange
1.3% Global Notes due 2029	BAX 29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☑	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicete by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The aggregate market value of the voting common equity held by non-affiliates of the registrant as of June 30, 2022 (the last business day of the registrant's most recently completed second fiscal quarter), based on the per share closing sale price of $64.23 on that date and the assumption for the purpose of this computation only that all of the registrant's directors and executive officers are affiliates, was approximately $32 billion. The number of shares of the registrant's common stock, $1.00 par value, outstanding as of January 31, 2023 was 504,672,166.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive 2023 proxy statement for use in connection with its Annual Meeting of Stockholders expected to be held on May 2, 2023 are incorporated by reference into Part III of this report.

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PART I

Item 1. *Business.*

Company Overview

Baxter International Inc., through its subsidiaries, provides a broad portfolio of essential healthcare products, including acute and chronic dialysis therapies; sterile intravenous (IV) solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; surgical hemostat and sealant products, advanced surgical equipment; smart bed systems; patient monitoring and diagnostic technologies; and respiratory health devices. These products are used by hospitals, kidney dialysis centers, nursing homes, rehabilitation centers, doctors' offices and by patients at home under physician supervision. Our global footprint and the critical nature of our products and services play a key role in expanding access to healthcare in emerging and developed countries. As of December 31, 2022, we manufactured products in over 20 countries and sold them in over 100 countries.

Baxter International Inc. was incorporated under Delaware law in 1931. As used in this report, "Baxter International" means Baxter International Inc. and "we", "our" or "us" means Baxter International and its consolidated subsidiaries, unless the context otherwise requires.

Recently Announced Strategic Actions

In January 2023, we announced the following planned strategic actions that are intended to enhance our operational effectiveness, accelerate innovation and drive additional stockholder value: (a) a proposed spinoff of our Renal Care and Acute Therapies product categories into an independent publicly traded company, (b) our development of a new operating model to simplify our operations and (c) our pursuit of strategic alternatives (including a potential sale) for our BioPharma Solutions (BPS) product category.

This proposed spinoff of our Renal Care and Acute Therapies product categories (the proposed spinoff) is currently expected to be completed during the first half of 2024, approximately 12 to 18 months from the date of the related announcement. In 2022 we generated $4.4 billion of combined net sales from our Renal Care and Acute Therapies product categories, representing approximately 29% of our consolidated net sales. We intend for the proposed spinoff to qualify as tax-free to Baxter and our shareholders for U.S. federal income tax purposes. The proposed spinoff is subject to the satisfaction of customary conditions, including final approval from our Board of Directors, the filing and effectiveness of a registration statement on Form 10, receipt of an Internal Revenue Service (IRS) ruling or related tax opinions from counsel, satisfactory completion of financing arrangements, consultations with works councils and other employee representative bodies and any necessary regulatory approvals.

To strengthen our ability to deliver on our vision to transform healthcare, we are designing a new operating model intended to simplify and streamline our operations. Once the simplified model is implemented, we expect to be a more integrated and nimble organization that can respond more effectively to changes in the macroeconomic environment, while enhancing our ability to drive innovation in our product portfolio. As part of these actions, we are working to create a more resilient supply chain and better align our manufacturing footprint and supply chain to our commercial activities. Under the new model, our business will be managed across four global business units consisting of: (1) Medical Products and Therapies, which will include our Medication Delivery, Advanced Surgery and Clinical Nutrition product categories, (2) Healthcare Systems and Technologies, which will include the Patient Support Systems, Front Line Care and Global Surgical Solutions product categories obtained in the Hillrom acquisition, (3) Pharmaceuticals, which will include our BPS product category, for which we are exploring strategic alternatives, and our Pharmaceuticals product category and (4) Kidney Care, which will include our Renal Care and Acute Therapies product categories that we are proposing to spinoff into an independent publicly traded company.
We expect to have our new organizational designs substantially finalized in the second quarter of 2023. The new operating model will have significant impacts on our systems and processes across our entire company and we expect to have those broader operational changes, including our updated management reporting framework for the new operating model, fully implemented during the second half of 2023. At that time, we expect that our reportable segments will be changed to align with the new operating model.

We are pursuing strategic alternatives (including a potential sale) for our BPS product category, which includes contract manufacturing services provided to pharmaceutical and biopharmaceutical companies. In 2022 we generated $644 million of net sales from that product category, representing approximately 4% of our consolidated net sales. A potential sale of, or other strategic transaction involving, BPS would help us further narrow our strategic focus as a company while providing an opportunity for capital deployment, including debt repayment.

Following these planned strategic actions (including completion of the proposed spinoff), we intend to emerge as a stronger hospital solutions and connected care company. As a more focused business, we expect to be better positioned to make strategic investments to accelerate our vision and to deliver differentiated value to our stakeholders with our unique combination of products, therapies and connected care platforms.

There can be no guarantees that the proposed spinoff, the simplified operating model or the sale of, or other strategic transaction involving, our BPS product category will be completed in the manner or over the timeframes described above, or at all.

Acquisition of Hillrom

On December 13, 2021, we completed our acquisition of all outstanding equity interests of Hill-Rom Holdings, Inc. (Hillrom) for a purchase price of $10.5 billion. Including the assumption of Hillrom's outstanding debt obligations, the enterprise value of the transaction was approximately $12.8 billion. Hillrom was a global medical technology leader and its products and services help enable earlier diagnosis and treatment, optimize surgical efficiency, and accelerate patient recovery while simplifying clinical communication and shifting care closer to home. Hillrom made those outcomes possible through digital and connected care solutions and collaboration tools, including smart bed systems, patient monitoring and diagnostic technologies, respiratory health devices, advanced equipment for the surgical space and more, delivering actionable, real-time insights at the point of care. In 2022 the Patient Support Systems, Front Line Care and Global Surgical Solutions product categories of our Hillrom segment collectively generated net sales of $2.9 billion. During 2022, we also recognized $2.8 billion of goodwill impairments and $332 million of indefinite-lived intangible asset impairments related to goodwill and trade name intangible assets that arose from the Hillrom acquisition. See Notes 2, 4, 5 and 17 in Item 8 of this Annual Report on Form 10-K for additional information about the Hillrom acquisition, goodwill and intangible asset impairments, Hillrom acquisition financing arrangements and Hillrom segment results, respectively.

Business Segments and Products

We currently manage our global operations based on four segments, consisting of the following geographic segments related to our legacy Baxter business: Americas (North and South America), EMEA (Europe, Middle East and Africa) and APAC (Asia-Pacific), and a global segment for our recently acquired Hillrom business. As discussed above under "Recently Announced Strategic Actions," we are designing a new operating model intended to simplify and streamline our operations and we expect that our reportable segments will be changed to align with that new operating model when it is fully implemented.

The Americas, EMEA and APAC segments provide a broad portfolio of essential healthcare products, including acute and chronic dialysis therapies; sterile IV solutions; infusion systems and devices; parenteral nutrition therapies; inhaled anesthetics; generic injectable pharmaceuticals; and surgical hemostat and sealant products. As discussed above under "Recently Announced Strategic Actions," we are pursuing the proposed spinoff of our Renal Care and Acute Therapies product categories and strategic alternatives for our BPS product category. The Hillrom segment provides digital and connected care solutions and collaboration tools, including smart bed systems, patient monitoring and diagnostic technologies, respiratory health devices and advanced equipment for the surgical space.

For financial information about our segments, see Note 17 in Item 8 of this Annual Report on Form 10-K.

Business Strategy

Our business strategy is focused on driving sustainable growth and innovation aligned with our mission to save and sustain lives and our vision to transform healthcare with a customer focus to improve patient outcomes, enhance workflow efficiency, and enable cost-effective care. Our diversified and broad portfolio of medical products that treat life-threatening acute or chronic conditions and our global presence are core components of our strategy as we

work to achieve these objectives. We are focused on four strategic pillars as part of our pursuit of industry leading performance: innovation; market expansion; operational efficiency; and capital allocation.

Innovation

Our innovation strategy is focused on connected care and core therapies offerings. Connected care offerings include devices or software that can connect, communicate and/or analyze data to help transform healthcare and improve patient outcomes. Our acquisition of Hillrom has been a key driver in developing our connected care offerings, as its product portfolio includes digital and connected care solutions and collaboration tools such as smart bed systems, patient monitoring and diagnostic technologies, respiratory health devices, advanced equipment for the surgical space and more, delivering actionable, real-time insights at the point of care. Our core therapies product offerings include medical devices and consumable medical products designed to address essential patient and provider needs across the continuum of care.

As part of this strategy and consistent with our recently announced strategic initiatives, we are shifting our investments to drive innovation in product areas where we have compelling opportunities to serve patients and healthcare professionals while advancing our business. We are accelerating the pace in which we bring these advances to market to support our future growth. We are in the midst of launching several new products, geographic expansions and line extensions including in such areas as chronic and acute renal care, smart pump technology, hospital pharmaceuticals and nutritionals, surgical sealants, smart beds, respiratory vests and more. These comprise a mix of entirely new offerings, improvements on existing technologies and the expansion of current products into new geographies.

Market Expansion

The market expansion component of our strategy includes capturing revenue synergies through the integration of Hillrom, expanding our portfolio geographically, broadening our portfolio through channel expansion and increasing utilization of our products and therapies through market development activities. These initiatives include using Baxter's geographic footprint to introduce the Hillrom product portfolio into new markets, as well as expanding value-added services, increasing adoption of underpenetrated therapies and providing education and advocacy to improve access to our products.

Operational Excellence

As discussed above under "Recently Announced Strategic Actions," we are designing a new operating model intended to simplify and streamline our operations. Once the simplified model is implemented, we expect to be a more integrated and nimble organization that can respond more effectively to changes in the macroeconomic environment, while enhancing our ability to drive innovation in our product portfolio. As part of these actions, we are working to create a more resilient supply chain and better align our manufacturing footprint and supply chain to our commercial activities. We also continue to focus on increasing efficiencies through automation and digitization and we remain committed to deliver on the targeted cost synergies expected to be achieved from our acquisition of Hillrom. We intend to continue to actively manage our cost structure to help ensure that we are committing resources to the highest value uses. Such high value activities include supporting innovation, building out the portfolio, expanding patient access and accelerating growth for our stockholders.

Maintaining Disciplined and Balanced Capital Allocation

Subject to market conditions and our investment grade targets, our capital allocation strategies include the following:

- debt repayments to support our deleveraging commitments;
- active portfolio management through the identification of attractive acquisition and divestiture transactions, including our recent acquisition of Hillrom, the proposed spinoff and our pursuit of strategic alternatives (including a potential sale) for our BPS product category; and
- return capital to stockholders through dividends. We also intend to reinstate share repurchases over the longer term.

We paid down approximately $900 million of debt during 2022 and we continue to be committed to an investment grade rating, including taking actions toward achieving our 2.75x net leverage commitment. We currently expect to apply proceeds from the proposed spinoff and potential BPS divestiture toward reducing indebtedness and addressing near-term debt maturities. During this deleveraging period, we currently intend to maintain our dividend, not make any share repurchases and be highly selective with respect to any potential acquisitions.

Sales and Distribution

We have our own direct sales force and also make sales to and through independent distributors, drug wholesalers acting as sales agents and specialty pharmacy or other alternate site providers. In the United States, third parties, such as Cardinal Health, Inc., warehouse and ship a significant portion of our products through their distribution centers. These centers are generally stocked with adequate inventories to facilitate prompt customer service. Sales and distribution methods include frequent contact by sales and customer service representatives, automated communications via various electronic purchasing systems, circulation of catalogs and merchandising bulletins, direct-mail campaigns, trade publication presence and advertising.

Sales are made and products are distributed on a direct basis or through independent distributors or sales agents in more than 100 countries as of December 31, 2022.

International Operations

The majority of our revenues are generated outside of the United States and geographic expansion remains a component of our strategy (including with respect to the Hillrom business). Our international presence includes operations in Europe, the Middle East, Africa, Asia-Pacific, Latin America and Canada. We are subject to certain risks inherent in conducting business outside the United States. For more information on these risks, see the information under the captions "Risks Related to Baxter's Business —We are subject to risks associated with doing business globally" and "—Changes in foreign currency exchange rates and interest rates could have a material adverse effect on our operating results and liquidity" in Item 1A of this Annual Report on Form 10-K.

For financial information about our foreign and domestic revenues and segment information, see Notes 10 and 17, respectively, in Item 8 of this Annual Report on Form 10-K. For more information regarding foreign currency exchange risk, refer to the discussion under the caption entitled "Financial Instrument Market Risk" in Item 7 of this Annual Report on Form 10-K.

Contractual Arrangements

Our products are sold through contracts with customers, both within and outside the United States. Some of these contracts have terms of more than one year and place limits on our ability to increase prices. In the case of hospitals, governments and other facilities, these contracts may specify minimum quantities of a particular product or categories of products to be purchased by the customer.

In keeping with the increased emphasis on cost-effectiveness in healthcare delivery, many hospitals and other customers of medical products in the United States have joined group purchasing organizations (GPOs), or formed integrated delivery networks (IDNs), to enhance purchasing power. GPOs and IDNs negotiate pricing arrangements with manufacturers and distributors and the negotiated prices are made available to members. We have purchasing agreements with several of the major GPOs in the United States. GPOs may have agreements with more than one supplier for certain products. Accordingly, in these cases, we face competition from other suppliers even where a customer is a member of a GPO under contract with us. Purchasing power is similarly consolidated in many other countries. For example, public contracting authorities often act as the purchasing entities for the hospitals and other customers of medical products in their region and many hospitals and other customers have joined joint procurement entities and buying consortia. The result is that demand for healthcare products is increasingly concentrated across our markets globally. Additionally, our contractual pricing arrangements with GPOs, IDNs and public contracting authorities limit our ability to increase prices in order to offset raw materials or component price increases or otherwise.

Raw Materials and Component Parts

Raw materials and component parts essential to our business are purchased from numerous suppliers worldwide in the ordinary course of business. While many of these materials are generally available, we have experienced and may in the future experience shortages of supply. Additionally, certain of these materials are secured from single

source suppliers or on a spot basis and not pursuant to a contractual arrangement. In recent periods, we have experienced increased costs and shortages of raw materials and component parts (including resins and electromechanical devices), which has had a negative impact on our profit margins, due to the increased costs, and on our sales for certain product categories, due to our inability to fully satisfy demand.

In an effort to manage risk associated with raw materials and component supply, we work closely with our suppliers to help ensure availability and continuity of supply while maintaining high quality and reliability. We also seek to develop new and alternative sources of supply where beneficial to our overall raw materials procurement strategy. Refer to Item 1A. Risk Factors of this Annual Report on Form 10-K for further information regarding risks related to the supply chain, raw materials and component parts.

We are not always able to recover cost increases for raw materials and component parts through customer pricing due to contractual limits, where applicable, and market forces. This circumstance occurred during 2022 and our profit margins were adversely impacted because we were unable to fully offset all such cost increases through customer pricing adjustments or other pricing actions. We seek to utilize long-term supply contracts with some suppliers to help maintain continuity of supply and manage the risk of price increases. Our ability to do so in the face of limited supply of certain raw materials and component parts and inflationary environment may be limited.

Competition and Healthcare Cost Containment

Our businesses benefit from a number of competitive advantages, including the breadth and depth of our product offerings and our strong relationships with customers, including hospitals and clinics, GPOs, IDNs, physicians and patients, many of whom self-administer home-based therapies that we supply. We also benefit from efficiencies and cost advantages resulting from shared manufacturing facilities and the technological advantages of our products.

Although no single company competes with us in all of our businesses, we face substantial competition in each of our segments from international and domestic healthcare, medical products and pharmaceutical companies and providers of all sizes, and these competitors often differ across our businesses. In addition, global and regional competitors continue to expand their manufacturing capacity and sales and marketing channels. We believe customer purchasing decisions are primarily focused on cost-effectiveness, price, service, product performance and technological innovation. There has been increasing consolidation in our customer base and by our competitors, which continues to result in pricing and market pressures.

Global efforts toward healthcare cost containment continue to exert pressure on product pricing. Governments around the world use various mechanisms to control healthcare expenditures, such as price controls, the formation of public contracting authorities, product formularies (lists of recommended or approved products), and competitive tenders which require the submission of a bid to sell products. Sales of our products are dependent, in part, on the availability of reimbursement by government agencies and healthcare programs, as well as insurance companies and other private payers. In the United States, the federal and many state governments have adopted or proposed initiatives relating to Medicaid and other health programs that may limit reimbursement or increase rebates that we and other providers are required to pay to the state. In addition to government regulation, managed care organizations in the United States, which include medical insurance companies, medical plan administrators, health-maintenance organizations, hospital and physician alliances and pharmacy benefit managers, continue to put pressure on the price and usage of healthcare products. Managed care organizations seek to contain healthcare expenditures, and their purchasing strength has been increasing due to their consolidation into fewer, larger organizations and a growing number of enrolled patients. We face similar issues outside of the United States. In Europe and Latin America, for example, the government provides healthcare at low cost to patients, and controls its expenditures by purchasing products through public tenders, collective purchasing, regulating prices, setting reference prices in public tenders or limiting reimbursement or patient access to certain products. For further discussion, refer to Item 1A of this Annual Report on Form 10-K.

Intellectual Property

Patents and other proprietary rights are essential to our business. We rely on patents, trademarks, copyrights, trade secrets, know-how and confidentiality agreements to develop, maintain and strengthen our competitive position. We own a number of patents and trademarks throughout the world and have entered into license arrangements relating to various third-party patents and technologies. Products manufactured by us are sold primarily under our own trademarks and trade names. Some products distributed by us are sold under our trade names, while others are sold under trade names owned by our suppliers or partners. Trade secret protection of unpatented confidential and proprietary information is also important to us. We maintain certain details about our processes, products and

technology as trade secrets and generally require employees, consultants, and business partners to enter into confidentiality agreements. These agreements may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, and business partners use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our policy is to protect our products and technology through patents and trademarks on a worldwide basis. This protection is sought in a manner that balances the cost of such protection against obtaining the greatest value for us. We also recognize the need to promote the enforcement of our patents and trademarks and take commercially reasonable steps to enforce our patents and trademarks around the world against potential infringers, including judicial or administrative action where appropriate.

We operate in an industry susceptible to significant patent litigation. At any given time, we are involved as either a plaintiff or defendant in a number of patent infringement and other intellectual property-related actions. Such litigation can result in significant royalty or other payments or result in injunctions that can prevent the sale of products. For more information on patent and other litigation, see Note 7 in Item 8 of this Annual Report on Form 10-K.

Research and Development

Our investment in research and development (R&D), consistent with our portfolio optimization and capital allocation strategies, helps fuel our future growth and our ability to remain competitive in each of our product categories. Accordingly, we continue to focus our investment on select R&D programs to enhance future growth through clinical differentiation. Expenditures for our R&D activities were $605 million in 2022, $534 million in 2021, and $521 million in 2020. These expenditures include costs associated with R&D activities performed at our R&D centers located around the world, which include facilities in Belgium, Sweden, India, Italy, Germany, China, Japan and the United States, as well as in-licensing, milestone and reimbursement payments made to partners for R&D work performed at non-Baxter locations. As discussed above in under "Recently Announced Strategic Actions," we are designing a new operating model intended to simplify and streamline our operations. We are also working to create a more resilient supply chain and better align our manufacturing footprint and supply chain to our commercial activities. These activities may result in the consolidation of one or more R&D facilities.

For more information on our R&D activities, refer to the discussion under the caption entitled "Strategic Objectives" in Item 7 of this Annual Report on Form 10-K.

Quality Management

Our continued success depends upon the quality of our products. Quality management plays an essential role in determining and meeting customer requirements, helping to prevent defects, facilitating continuing improvement of our processes, products and services, and helping to assure the safety and efficacy of our products. Our quality system enables the design, development, manufacturing, packaging, sterilization, handling, distribution and labeling of our products to ensure that they conform to customer requirements. In order to consistently improve the effectiveness and efficiency of our quality system, various measurement, monitoring and analysis methods, such as management reviews and internal, external and vendor audits, are employed at local and central levels.

Each product that we market is required to meet specific quality standards, both in packaging and in product integrity and quality. If any of those is determined to be compromised at any time, we endeavor to take corrective and preventive actions designed to ensure compliance with regulatory requirements and to meet customer expectations. For more information on corrective actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

Corporate Responsibility

Driven by our mission to save and sustain lives, Baxter's corporate responsibility strategy focuses on addressing the environmental, social and governance (ESG) issues that affect our patients, customers, employees, communities and other stakeholders worldwide. Our corporate responsibility approach supports our business priorities to achieve top quartile results relative to industry peers and other comparators across four dimensions: patient safety and quality, growth through innovation, best place to work and industry-leading performance. Advancing our corporate responsibility goals contributes to business, social and economic value, including attraction and retention, enhanced operational efficiency and implementation of enterprise risk management strategies, among others.

In 2021, we launched our 2030 Corporate Responsibility Commitment featuring ten strategic goals for focused action. Our Commitment is anchored by three pillars - Empower Our Patients, Protect Our Planet and Champion Our People and Communities - and bolstered by our approach to the foundational principles of Ethics and Compliance, Human Rights, Diversity, Equity and Inclusion and Privacy and Data Protection. The 2030 Corporate Responsibility Commitment and Goals highlight Baxter's corporate responsibility focus and help to further advance our ESG performance. Our progress against these goals is published annually in our Corporate Responsibility Report which is available on our website under "Our Story-Corporate Responsibility." The Corporate Responsibility Report is not incorporated by reference into this Annual Report on Form 10-K or any other document filed with the SEC.

Government Regulation

Our operations and many of the products manufactured or sold by us are subject to extensive regulation by numerous government agencies, both within and outside the United States. The Food and Drug Administration (FDA) in the United States, the European Medicines Agency (EMA) in Europe, the China Food and Drug Administration (CFDA) in China and other government agencies, inside and outside of the United States, administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of our products. We must obtain specific approval from FDA and non-U.S. regulatory authorities before we can market and sell most of our products in a particular country. Even after we obtain regulatory approval to market a product, the product and our manufacturing processes and quality systems are subject to continued review by FDA and other regulatory authorities globally, including additional 510(k) and other regulatory submissions, and approvals or the time needed to secure approvals are not certain. State agencies in the United States also regulate our facilities, operations, employees, products and services within their respective states. We, along with our facilities, are subject to periodic inspections and possible administrative and legal actions by FDA and other regulatory agencies inside and outside the United States. Such actions may include warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. As situations require, we take steps to ensure safety and efficacy of our products, such as removing products found not to meet applicable requirements from the market and improving the effectiveness of quality systems. For more information on compliance actions taken by us, refer to the discussion under the caption entitled "Certain Regulatory Matters" in Item 7 of this Annual Report on Form 10-K.

We are also subject to various laws inside and outside the United States concerning our relationships with healthcare professionals and government officials, price reporting and regulation, the promotion, sales and marketing of our products and services, the importation and exportation of products, the operation of our facilities and distribution of products. In the United States, we are subject to the oversight of FDA, Office of the Inspector General within the Department of Health and Human Services (OIG), the Center for Medicare/Medicaid Services (CMS), the Department of Justice (DOJ), Environmental Protection Agency, Department of Defense and Customs and Border Protection in addition to others. We supply products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare. As a result, our activities are subject to regulation by CMS and enforcement by OIG and DOJ. In each jurisdiction outside the United States, our activities are subject to regulation by government agencies including the EMA in Europe, CFDA in China and other agencies in other jurisdictions. Many of the agencies enforcing these laws have increased their enforcement activities with respect to healthcare companies in recent years. These actions appear to be part of a general trend toward increased enforcement activity globally.

Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. Our environmental policies require compliance with all applicable environmental regulations and contemplate, among other things, appropriate capital expenditures for environmental protection. For example, we made $6 million, $33 million and $10 million of capital expenditures in 2022, 2021 and 2020, respectively, related to a new ethylene oxide emissions control system at our Mountain Home, Arkansas facility that was substantially completed in 2022.

Human Capital Management

As of December 31, 2022, we employed approximately 60,000 people globally, with approximately 19,000 employees in the United States and approximately 41,000 employees outside of the United States. Our employees are our most important assets and set the foundation for our ability to achieve our strategic objectives. They contribute to our success and are instrumental in driving operational execution and our ability to deliver strong

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: X4 Pharmaceuticals, Inc.

Physical Address: 61 North Beacon Street, 4th Floor

City: Boston State: MA Zip: 02134

Mailing Address (if different from physical address): 61 North Beacon Street, 4th Floor

City: Boston State: MA Zip: 02134

Telephone: (857) 529-8300 Website: www.x4pharma.com

Name of Designated Representative (DR): Karen Dobson

Licensing Company Email: x4licensing@x4pharma.com DR Email: karen.dobson@x4pharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty pharmacies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): X4 Pharmaceuticals, Inc.

Corporation Name: X4 Pharmaceuticals, Inc.

Mailing Address: 61 North Beacon Street, 4th Floor

City: Boston State: MA Zip: 02134

Telephone: (857) 529-8300 Email: x4licensing@x4pharma.com

Contact Person Name: Karen Dobson

Date of SEC Registration: 9/24/2010	SEC Registration Number: 1501697	Stock Exchange Symbol: XFOR

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

X4 Pharmaceuticals, Inc.
Facility Name

Mark Baldry
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Oct 03, 2023
Date

Board Use Only	Date Received: 10/11/23	Amount: $1000 check 122

PHARMACEUTICALS

Description of Operations

X4 Pharmaceuticals, Inc. is a Virtual Manufacturer. X4 Pharmaceutical's products are manufactured by a Contract Manufacturer and will be distributed to patients by their Third-Party Logistics Provider, Amerisource Bergen, ICS, who is licensed to ship pharmaceutical products into your state. Sales records are stored at the 3PL. We are using the following contract manufacturer to produce our product:

Catalent Greenville, Inc.
1240 Sugg Parkway
Greenville, NC 27834
FDA Establishment Number: 300209735

Contact Person: Ed Szczesny
Contact Number (617) 436-3839

Catalent Greenville, Inc. manufactures X4 Pharmaceutical's product and packages finished product. At no time does Catalent Greenville, Inc. own the product, contract with X4 Pharmaceutical's customers, invoice, nor sell a X4 Pharmaceutical's product. X4 Pharmaceutical's products are not Controlled Substances.

Labeler Code: 83296 √ Verified M.H 12/15/23

Third Party Logistic information:
For distribution into the commercial supply channels, Amerisource Bergen, ICS, acts as X4 Pharmaceuticals, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of X4's's product throughout the United States.

Amerisource Bergen, ICS
420 International Blvd Ste 500, Brooks, KY 40109
Contact Person: Joshua Sutherland
502-955-3626

X4 Pharmaceuticals has 70 employees working on site during normal business hours.
X4 Pharmaceuticals' hours of operation are 9:00 am – 5:00pm Monday through Friday.

From: edrls@fda.hhs.gov
To: Kathleen Galvez
Subject: [EXTERNAL] Labeler Code Request Approved
Date: Wednesday, February 22, 2023 3:35:36 PM

CAUTION - This message originated from outside the organization. Please exercise caution when following links or opening attachments.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 22-FEB-2023
Labeler DUNS: 080014773
Labeler Name: X4 Pharmaceuticals, Inc.
Labeler Code Assigned: 83296

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Company Information

X4 Pharmaceuticals, Inc.
61 North Beacon Street, 4th Floor
Boston, MA 02134
(857) 529-8300
x4licensing@x4pharma.com
FEIN: 27-3181608
State of Formation: Delaware
Date Incorporated: 8/2/2010

Ownership Information

X4 Pharmaceuticals, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol XFOR.

Officers

Paula Ragan, PhD. President and Chief Executive Officer
Business Address: 61 North Beacon Street 4th Floor, Boston MA 02474
Business Phone: (857) 529-8301

Mary DiBiase, Chief Operating Officer
Business Address: 61 North Beacon Street 4th Floor, Boston MA 02474
Business Phone: (857) 341-1039 Ext.8828

Mark Baldry, Chief Commercial Officer
Business Address: 61 North Beacon Street 4th Floor, Boston MA 02474
Business Phone: (857) 472-3431

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "X4 PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "X4 PHARMACEUTICALS, INC." WAS INCORPORATED ON THE SECOND DAY OF AUGUST, A.D. 2010.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4851982 8300

SR# 20233875127

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204571408

Date: 11-11-23

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

X4 Pharmaceuticals, Inc
61 North Beacon Street , 4th Floor
Boston, MA 02134

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200019

Type: Virtual Manufacturer

Issue Date: 04/24/2023

Expiration Date: 04/24/2024

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

The system will be offline for updates Tuesday, October 24th from 6:00pm to 6:30pm.

An official website of the Commonwealth of Massachusetts Here's how you know

Mass.gov Office of Health and Human Services (EOHHS) License Verification Site

Home Page > Profile > VIR200019 - X4 Pharmaceuticals, Inc

License Information

License Type:	Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration
License Number:	VIR200019
Status:	Current
Organization Name:	X4 Pharmaceuticals, Inc
Expiration Date:	April 24, 2024
Address:	61 North Beacon Street 4th Floor Boston, MA 02134

Compliance Actions/Fines

There are no public compliance actions or fines against this license/registration record.

Verification of Licensure

To generate a Verification of Licensure for this license/registration record, please click the "Generate Verification of Licensure" button below.

Generate Verification of Licensure

Disclaimer: The information contained in this website ("website content") is made available as a public service by the Massachusetts Department of Public Health (the Department). The Department considers this information to constitute primary source verification. Click here for full disclaimer.

<< Back to Search Page

How To Get Help:

Mass.gov Resources

eLicensing User Guide
Bureau of Health Professions Licensure
Office of Local and Regional Health
Department of Public Health

BHPL eLicensing Support Resources

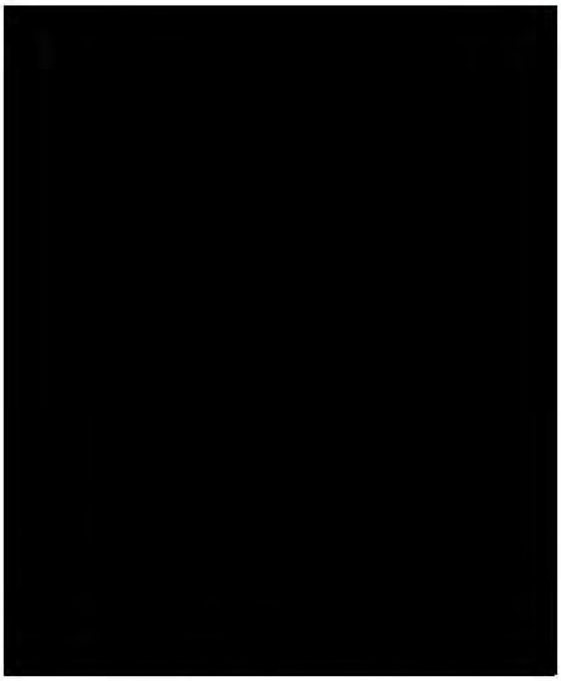
Online:eLicensing Support Request Form
Email:dph.elicensing_support@mass.gov

DO NOT provide your Social Security Number or **Date of Birth** when contacting the eLicensing Support Desk online or by email

CONFIDENTIAL

Employee list:

[redacted]



The content of this documnt is confidential and it not to be used beyond its intended use.

X4 License List				
Licensing State	License Type	License #	Issue Date	Expiration Date
Massachusetts	Virtual Manufacturer	VIR200019	4/23/2023	4/24/2024
West Virginia	Manufacturer	MR0552481	6/6/2023	6/30/2024

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "X4 PHARMACEUTICALS, INC.", FILED IN THIS OFFICE ON THE FIRST DAY OF SEPTEMBER, A.D. 2022, AT 12:04 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

4851982 8100
SR# 20223422842

Authentication: 204299394
Date: 09-01-22

You may verify this certificate online at corp.delaware.gov/authver.shtml

CERTIFICATE OF AMENDMENT OF THE RESTATED CERTIFICATE OF INCORPORATION OF X4 PHARMACEUTICALS, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

X4 Pharmaceuticals, Inc. (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"),

DOES HEREBY CERTIFY:

1. A resolution was duly adopted by the Board of Directors of the Corporation pursuant to Section 242 of the General Corporation Law proposing this Amendment of the Corporation's Restated Certificate of Incorporation and declaring the advisability of this Amendment of the Restated Certificate of Incorporation, and authorizing the appropriate officers of the Corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment is as follows:

RESOLVED, that the first paragraph of Article FOURTH of the Restated Certificate of Incorporation of the Corporation, as amended, be and hereby is deleted in its entirety and the following paragraphs are inserted in lieu thereof:

"FOURTH. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 510,000,000 shares, consisting of (i) 500,000,000 shares of Common Stock, $0.001 par value per share ("Common Stock"), and (ii) 10,000,000 shares of Preferred Stock, $0.001 par value per share ("Preferred Stock")."

2. This Certificate of Amendment of the Restated Certificate of Incorporation has been duly adopted by the stockholders of the Corporation in accordance with the provisions of Section 242 of the General Corporation Law.

[Remainder of page intentionally blank]

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:04 PM 09/01/2022
FILED 12:04 PM 09/01/2022
SR 20223422842 - File Number 4851982

IN WITNESS WHEREOF, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 1st day of September, 2022.

/s/ Paula Ragan
Paula Ragan, Ph.D.
President and Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 27, 2023**

X4 PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38295**	**27-3181608**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

61 North Beacon Street, 4th Floor
Boston, Massachusetts **02134**
(Address of principal executive offices) **(Zip Code)**

(857) 529-8300
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	**XFOR**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

On November 27, 2023, X4 Pharmaceuticals, Inc. (the "Company") posted an updated corporate presentation on the Company's website. To access the presentation, investors should visit the "Investors" section of the Company's website at www.x4pharma.com.

The information furnished under this Item 7.01 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

October 23, 2023

Via Fed Ex
Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, NV,89509

On behalf of X4 Pharmaceuticals, Inc., attached is X4's application for initial state licensure as a Virtual Manufacturer.

X4 Pharmaceuticals, Inc. is a Virtual Manufacturer. X4 Pharmaceutical's products are manufactured by a Contract Manufacturer and will be distributed to patients by their Third-Party Logistics Provider, Amerisource Bergen, ICS, who is licensed to ship pharmaceutical products into your state. Sales records are stored at the 3PL. We are using the following contract manufacturer to produce our product, Catalent Greenville, Inc.

X4 is a Virtual Manufacturer whose products are manufactured by a contract manufacturer and distributed by a Third-Party Logistics, who meets licensure requirements to ship pharmaceutical products into your state. At no time is commercial product manufactured at, stored at, or distributed from X4's office. X4's product isn't a controlled substance. Accordingly, X4 is not required to obtain a DEA registration. At the time of this filing, X4 only holds a license in their home state of Massachusetts.

I hope this narrative is helpful as you review X4's application. If you have a question regarding this application, please contact me at 614-519-4775 or via email at erin.vorisek@twolabs.com. Please also address all written communication to me. My address is 6290 Needle tail RD, Columbus oh 43230.

Thank you in advance for your consideration.

Erin Vorisek
Licensing Analyst
PharmaLicense

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 1906 East Cedar Ave.

City: Ontario State: CA Zip: 91761

Mailing Address (if different from physical address): 1031 Mendota Heights Rd., Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-378-2024 Website: www.animalhealthinternational.com

Name of Designated Representative (DR): Matthew Harris

Licensing Company Email: FacilityLicensing@Pattersoncompanies.com DR Email: Matthew.Harris@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others: Veterinary Legend Drugs	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✔	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Boehringer Ingelheim
Address: PO Box 22748 City: New York State: NY Zip: 10087
Name: Elanco US Inc.
Address: 28576 Network Place City: Chicago State: IL Zip: 60673
Name: Merck Animal Health
Address: BOX 198428 City: Atlanta State: GA Zip: 30384
Name: Zoetis US LLC
Address: PO Box 419022 City: Boston State: MA Zip: 02241

Section 4: Publicly Traded Corporation

State of Incorporation: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road, Attn: Regulatory Licensing
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: FacilityLicensing@Pattersoncompanies.com
Contact Person Name: Kelley Karau

Date of SEC Registration: 05/13/1996	SEC Registration Number: 0-20572	Stock Exchange Symbol: PDCO

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** NA	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ NA	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). NA	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M. Pohlman

Print Name of Authorized Person Submitting Application

Kevin M. Pohlman

Original signature of Authorized Person (copies or stamps not accepted)

11/16/23

Date

Board Use Only	Date Received: 11/29/23	Amount: $1000-cc

ANIMAL HEALTH INTERNATIONAL, INC.

(LIST OF OFFICERS & DIRECTORS)

DIRECTORS

Donald J. Zurbay	1031 Mendota Heights Rd, St. Paul, MN 55120
Les B. Korsh	1031 Mendota Heights Rd, St. Paul, MN 55120

OFFICERS

Donald J. Zurbay	CEO	1031 Mendota Heights Rd, St. Paul, MN 55120
Kevin M. Pohlman	President	[redacted]
Kevin M. Barry	VP, CFO & Treasurer	1031 Mendota Heights Rd, St. Paul, MN 55120
Les B. Korsh	Corporate Secretary	1031 Mendota Heights Rd, St. Paul, MN 55120

Incorporated - Minnesota
Date - 3/22/96
Federal ID# - 41-1833619

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc. 1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515

Animal Health International, Inc. – Top Shareholders

Corporate Address:	2915 Rocky Mountain Ave. Suite 400 Loveland, CO 80538
Phone:	970-353-2000
FEIN:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Facility:	Animal Health International, Inc.
Address:	1906 East Cedar Ave. Ontario, CA 91761

Shareholders:	BlackRock Fund Advisors	7.36%
	The Vanguard Group, Inc.	5.53%
	Dimensional Fund Advisors, L.P. (US)	10.96%
	State Street Global Advisors (SSgA)	5.64%

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 10/17/2023 that have been posted, and by documents delivered to this office electronically through 10/18/2023 @ 09:07:16 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 10/18/2023 @ 09:07:16 in accordance with applicable law. This certificate is assigned Confirmation Number 15410402 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal License

Wholesale Drug Permit

LICENSE NO. WLS 6863
RECEIPT NO. 00184279

VALID UNTIL APRIL 01, 2024

ANIMAL HEALTH INTERNATIONAL INC
1906 EAST CEDAR
ONTARIO CA 91761

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

02/01/23
02/07/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHALS (09/20) WI

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc. 1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515
Company:	Animal Health International, Inc.
Corporate Address:	2915 Rocky Mountain Ave. Suite 400 Loveland, CO 80538
Phone:	970-353-2000
FEIN:	84-0575063
State of Incorporation:	Colorado (5/16/1967)
Facility:	Animal Health International, Inc.
Address:	1906 East Cedar Ave. Ontario, CA 91761

Employees:

Bill Silva
Dan Swager
Doug Harris
Frank Enriquez Jr
Holly Maxwell
John Grisley Jr
Kathleen Turnbaugh
Larry Salazar
Lyndsi Dean
Matthew Harris
Rick Vandermeer
Russell Smith
Vanessa Prestsater

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended April 29, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 0-20572

PATTERSON COMPANIES, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**41-0886515**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1031 Mendota Heights Road
St. Paul, Minnesota 55120
(Address of principal executive offices including Zip Code)

Registrant's telephone number, including area code: (651) 686-1600

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $.01	PDCO	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐
Smaller reporting company	☐	Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☑

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (October 29, 2022) was approximately $2,521,000,000 (For purposes of this calculation all of the registrant's executive officers and directors are deemed affiliates.)

As of June 14, 2023, there were 95,294,000 shares of Common Stock of the registrant issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year-end of April 29, 2023 are incorporated by reference into Part III.

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PART I

Item 1. BUSINESS

Forward-Looking Statements

The U.S. Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information, so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those disclosed in the statement. Certain information of a non-historical nature contained in Items 1, 2, 3 and 7 of this Form 10-K includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding future financial performance, and the objectives and expectations of management. Forward-looking statements often include words such as "believes," "expects," "anticipates," "estimates," "intends," "plans," "seeks" or words of similar meaning, or future or conditional verbs, such as "will," "should," "could" or "may." Forward-looking statements are neither historical facts nor assurances of future performance. Instead, such statements, including, but not limited to, our statements regarding business strategy, growth strategy, competitive strengths, productivity and profitability enhancement, competition, new product and service introductions and liquidity and capital resources, are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions, as well as on assumptions made by and information currently available to management, and involve various risks and uncertainties, some of which are beyond our control.

Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not place undue reliance on any of these forward-looking statements. Any number of factors could affect our actual results and cause such results to differ materially from those contemplated by any forward-looking statements. Reference is made to "Risk Factors" in Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this Form 10-K, for a discussion of certain factors that could cause actual operating results to differ materially from those expressed in any forward-looking statements. In light of these risks and uncertainties, there can be no assurance that the forward-looking information will in fact prove to be accurate. The order in which these factors appear should not be construed to indicate their relative importance or priority. We caution that these factors may not be exhaustive, accordingly, any forward-looking statements contained herein should not be relied upon as a prediction of actual results.

You should carefully consider these and other relevant factors and information which may be contained in this Form 10-K and in our other filings with the U.S. Securities and Exchange Commission, or SEC, when reviewing any forward-looking statement. Investors should understand it is impossible to predict or identify all such factors or risks. As such, you should not consider the risks identified in our SEC filings, to be a complete discussion of all potential risks or uncertainties.

Any forward-looking statement made in this Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We do not undertake any obligation to release publicly any revisions to any forward-looking statements whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

General

Patterson Companies, Inc. is a value-added specialty distributor serving the U.S. and Canadian dental supply markets and the U.S., Canadian and U.K. animal health supply markets. Patterson operates through its two strategic business units, Patterson Dental and Patterson Animal Health, offering similar products and services to different customer bases. Each business has a strong competitive position, serves a highly fragmented market that offers consolidation opportunities and offers relatively low-cost consumable supplies, which makes our value-added business proposition highly attractive to our customers. We believe that we have a strong brand identity as a value-added, full-service distributor with broad product and service offerings, having begun distributing dental supplies in 1877.

Business Overview

The following table sets forth consolidated net sales (in millions) by segment.

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Dental	$ 2,492	$ 2,516	$ 2,327
Animal Health	3,965	3,983	3,560
Corporate	14	—	25
Consolidated net sales	$ 6,471	$ 6,499	$ 5,912

Our strategically located fulfillment centers enable us to better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs. Our infrastructure also allows us to provide convenient ordering and rapid, accurate and complete order fulfillment.

Electronic commerce solutions have become an integral part of dental and animal health supply and distribution relationships. Our distribution business is characterized by rapid technological developments and intense competition. The continuing advancement of online commerce requires us to cost-effectively adapt to changing technologies, to enhance existing services and to develop and introduce a variety of new services to address the changing demands of consumers and our customers on a timely basis, particularly in response to competitive offerings. We believe that our tradition of reliable service, our name recognition and large customer base built on solid customer relationships, position us well to participate in this significant aspect of the distribution business. We continue to explore methods to improve and expand our Internet presence and capabilities, including our online commerce offerings and our use of various social media outlets.

Patterson became publicly traded in 1992 and is a corporation organized under the laws of the state of Minnesota. We are headquartered in St. Paul, Minnesota. Our principal executive offices are located at 1031 Mendota Heights Road, St. Paul, Minnesota 55120, and our telephone number is (651) 686-1600. Unless the context specifically requires otherwise, the terms the "Company," "Patterson," "we," "us" and "our" mean Patterson Companies, Inc., a Minnesota corporation, and its consolidated subsidiaries.

The Specialty Distribution Markets We Serve

We provide manufacturers with cost effective logistics and high-caliber sales professionals to access a geographically diverse customer base, which is critical to the supply chain for the markets we serve. We provide our customers with an array of value-added services, a dedicated and highly skilled sales team, and a broad selection of products through a single channel, thereby helping them efficiently manage their ordering process. Due in part to the inability of our customers to store and manage large quantities of supplies at their locations, the distribution of supplies and small equipment has been characterized by frequent, small-quantity orders, and a need for rapid, reliable and substantially-complete order fulfillment. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

We believe that consolidation within the industry will continue as distributors, particularly those with limited financial, operating and marketing resources, seek to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

Dental Supply Market

The dental supply market we serve consists of geographically dispersed and highly fragmented dental practices. Customers range in size from sole practitioners to large group practices, often called Dental Service Organizations ("DSO's"). According to the American Dental Association and the Canadian Dental Association, there are approximately 203,000 dentists practicing in the U.S. and 25,000 dentists practicing in Canada. We believe the average dental practitioner purchases supplies from more than one supplier.

We believe the North American dental supply market continues to experience growth due to an increasing population, an aging population, advances in dentistry, demand for general, preventive and specialty services, increasing demand for new technologies that allow dentists to increase productivity, demand for infection control products, and insurance coverage by dental plans.

We support dental professionals through the many stock keeping units ("SKUs") that we offer, as well as through important value-added services, including equipment and technology installation and service, practice management software, electronic claims processing, financial services, and continuing education, all designed to help make a dental practice more efficient.

Animal Health Supply Market

The animal health supply market is a mix of production animal supply, which primarily serves food producing animals, consisting of beef and dairy cattle, swine and poultry and other species such as sheep and goats, and companion animal supply, which serves pets, primarily dogs, cats and horses. Similar to the dental supply market, the animal health supply market is highly fragmented and diverse. Our production animal customers include large animal veterinarians, beef producers (cow/calf, stocker and feedlots), dairy producers, poultry producers, swine producers and retail customers. Our companion animal customers are primarily small animal and equine veterinary clinics, including independently owned, corporates and groups. According to the American Veterinary Medical Association, there are more than 70,000 veterinarians in private practice in the U.S. and Canada. Furthermore, there are approximately 20,000 veterinarians in the U.K. practicing in veterinary outlets; however, we believe there has been a shift in the U.K. market toward consolidation of veterinary practices. National Veterinary Services Limited, is the market leader in the U.K. veterinary market, with the highest percentage of buying groups and corporations as customers compared to its competitors, and the highest share position in that country overall.

The global animal health supply market continues to experience growth, and we believe that trend will continue for the foreseeable future. We support our animal health customers through the distribution of biologicals, pharmaceuticals, parasiticides, supplies, including our own private label brands, and equipment. We also supply a full portfolio of technologies, software, services and solutions to all segments and channels of our broad customer base. We actively engage in the development, sale and distribution of inventory, accounting and health management systems to enhance customer operating efficiencies and assist our customers in managing risk. Within the companion animal supply market, we anticipate increasing demand for veterinary services due to the following factors: the increasing number of households with companion animals, increased pet adoption rates and increased expenditures on animal health and preventative care, an aging pet population, advancements in animal health products and diagnostic testing, and extensive marketing programs sponsored by companion animal nutrition and pharmaceutical companies.

We anticipate the macroeconomic trend of global population growth and corresponding demand for protein will be favorable to the production animal segment in the future. Likewise, the rise in disposable income, especially in developing countries will be a key driver of future growth. However; product sales in the production animal supply market are more likely to be impacted by volatility in the market such as commodity prices, changes in weather patterns, and trends in the general economy. Many factors can influence how long cattle will graze and consequently the number of days an animal is on feed during a finishing phase. Supply and demand dynamics and economic trends can shift the number of animals treated, the timing of when animals are treated, to what extent they are treated and with which products they are treated. Historically, sales in this market have been largely driven by spending on animal health products to improve productivity, weight gain and disease prevention, as well as a growing focus on health and wellness of the animals, safety, and efficiency in livestock production.

Competition

The distribution industry is highly competitive. It consists principally of national, regional and local full-service distributors. Substantially all of the products we sell are available to customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Some manufacturers also sell directly to end-users, thereby eliminating or reducing our role and that of other distributors.

We compete with other distributors, as well as several manufacturers, of dental and animal health products, on the basis of price, breadth of product line, customer service and value-added products and services. To differentiate ourselves from our competition we deploy a strategy of premium customer service with multiple value-added components, a highly qualified and motivated sales force, highly-trained and experienced service technicians, an extensive breadth and mix of products and services, technology solutions allowing customers to easily access our inventory, accurate and timely delivery of product, strategic location of sales offices and fulfillment centers, and competitive pricing.

In the U.S. and Canadian dental supply market, we compete against Henry Schein, Inc., Benco Dental Supply Company, Burkhart Dental Supply and hundreds of distributors that operate on a regional or local level, or online. Also, as noted above, some manufacturers sell directly to end users. With regard to our dental practice

management software, we compete against numerous offerings, including those from Henry Schein, Inc. and Carestream Dental.

In the U.S. and Canadian animal health supply market, our primary competitors are AmerisourceBergen/MWI Animal Health and Covetrus, Inc. We also compete against a number of regional and local animal health distributors, some manufacturers that sell direct to end users and several alternative channel market providers that sell through digital platforms to production animal operators, animal health product retailers and veterinarians. Additionally, major U.S. online e-commerce retailers such as Amazon and Chewy.com have become licensed as veterinary mail order pharmacies, which enables them to offer pharmacy products directly to consumers in all 50 U.S. states. In the animal health practice management market, our primary competitors are IDEXX Laboratories, Inc. and Covetrus, Inc. We face significant competition in the animal health supply market in the U.K., where we compete on the basis of price and customer service with several large competitors, including Covetrus, Inc. and AmerisourceBergen. We also compete directly with pharmaceutical companies who sell certain products or services directly to the customer.

Successful distributors are increasingly providing value-added services in addition to the products they have traditionally provided. We believe that to remain competitive we must continue to add value to the distribution channel, while removing unnecessary costs associated with product movement. Significant price reductions by our competitors could result in competitive harm. Any of these competitive pressures may materially adversely affect our operating results.

Competitive Strengths

We have more than 140 years of experience in distributing products resulting in strong awareness of the Patterson brand. Although further information regarding these competitive strengths is set forth below in the discussion of our two strategic business units, our competitive strengths include:

- *Broad product and service offerings at competitive prices.* We sell approximately 200,000 SKUs to our customers, including many proprietary branded products. We believe that our proprietary branded products and our competitive pricing strategy have generated a loyal customer base that is confident in our brands. Our product offerings include consumables, equipment, software and various technologies. Our value-added services include practice management software, office design, equipment installation and maintenance, and financing.

- *Focus on customer relationships and exceptional customer service.* Our sales and marketing efforts are designed to establish and solidify customer relationships through personal visits by field sales representatives, interaction via phone with sales representatives, web-based activities including e-commerce and frequent direct marketing, emphasizing our broad product lines, competitive prices and ease of order placement. We focus on providing our customers with exceptional order fulfillment and a streamlined ordering process.

- *Cost-effective purchasing and efficient distribution.* We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitive-pricing provider of dental and animal health products. We strive to maintain optimal inventory levels to satisfy customer demand for prompt and complete order fulfillment through our distribution of products from strategically located fulfillment centers.

Business Strategy

Our objective is to continue to expand as a leading value-added distributor of dental and animal health products and services. To accomplish this, we will apply our competitive strengths in executing the following strategies:

- *Emphasizing our differentiated, value-added, full-service capabilities.* We are positioned to meet virtually all of the needs of dental practitioners, veterinarians, production animal operators and animal health product retailers by providing a broad range of consumable supplies, technology, equipment, software and value-added services. We believe our knowledgeable sales representatives can create customer intimacy and loyalty by providing an informational, consultative approach to our customers, linking them to the industries we serve. Our value-added strategy is further supported by our equipment specialists who offer consultation on design, equipment requirements and financing, our service technicians who perform equipment installation, maintenance and repair services, our business development professionals who provide business tools and educational programs to our customers, and our technology advisors who provide guidance on integrating technology solutions.

- *Using technology to enhance customer service.* As part of our commitment to providing superior customer service, we offer our customers easy order placement. Although we offer computerized order entry systems that we believe help establish relationships with new customers and increase loyalty among existing customers, predominant platforms for ordering today include www.pattersondental.com, www.pattersonvet.com and www.animalhealthinternational.com. The use of these methods of ordering enables our sales representatives to spend more time with existing and prospective customers. Our Internet environment includes order entry, customer support for digital and our proprietary products, customer-loyalty program reports and services, and access to articles and manufacturers' product information. We also provide real-time customer and sales information to our sales force, managers and vendors via the Internet. In addition, the Patterson Technology Center ("PTC") differentiates Patterson from our competition by providing deep and thorough expertise in practice management software and other advanced equipment and technology clinical solutions. In addition to trouble-shooting through the PTC's support center, customers can access various service capabilities offered by the PTC, including electronic claims and statement processing and system back-up capabilities.

- *Continuing to improve operating efficiencies.* We continue to implement programs designed to improve our operating efficiencies and allow for continued sales growth. This strategy includes our continuing investment in management information systems and consolidation and leveraging of fulfillment centers and sales branches between our operating segments. In addition, we have established shared sales branch offices in several locations.

- *Growing through internal expansion and acquisitions.* We intend to continue to grow by hiring sales representatives, hiring and training sales professionals, opening additional locations as needed, and acquiring other companies in order to enter new, or more deeply penetrate existing, markets, gain access to additional product lines, and expand our customer base. We believe both of our operating segments are well positioned to take advantage of expected continued consolidation in our markets.

Dental Segment - Products, Services and Sources of Supply

Patterson Dental, one of the two largest distributors of dental products in North America, has operations in the U.S. and Canada. As a full-service, value-added supplier to over 100,000 dental practices, dental laboratories, educational institutions, and community health centers, Patterson Dental provides consumable products (including infection control, restorative materials, and instruments); basic and advanced technology and dental equipment; and innovative practice optimization solutions, including practice management software, e-commerce, revenue cycle management, patient engagement solutions, and clinical and patient education. Patterson Dental sells approximately 100,000 SKUs, of which approximately 3,500 are private-label products sold under the Patterson brand. Patterson Dental also offers customers a range of related services including software and design services, maintenance and repair, and equipment financing. Net sales and operating income were $2.5 billion and $237 million in fiscal 2023, respectively.

The following table sets forth the percentage of total sales by the principal categories of products and services offered to our dental segment customers:

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Consumable	55 %	57 %	56 %
Equipment	33	32	31
Value-added services and other	12	11	13
	100 %	100 %	100 %

Patterson Dental obtains products from hundreds of vendors, most of which are non-exclusive. While there is generally more than one source of supply for most of the categories of products we sell, the concentration of business with key suppliers is considerable, as consolidation has increased among manufacturers. In fiscal 2023, 2022 and 2021, Patterson Dental's top ten supply vendors accounted for approximately 58%, 56% and 57% of the total cost of sales, respectively. The top vendor accounted for 24%, 24% and 25% of the total cost of sales in fiscal 2023, 2022 and 2021, respectively.

Animal Health Segment - Products, Services and Sources of Supply

Patterson Animal Health is a leading distributor of animal health products in the U.S., Canada and the U.K. We sell approximately 100,000 SKUs, of which approximately 2,000 are private-label. Products are sourced from over 2,000 manufacturers to over 50,000 customers in the highly fragmented animal health supply market. Products we distribute include pharmaceuticals, vaccines, parasiticides, diagnostics, prescription and non-prescription diets, nutritionals, consumable supplies and equipment. We offer a private label portfolio of products to veterinarians, producers, and retailers through our Aspen, First Companion and Patterson Veterinary brands. We also provide a range of value-added services to our customers. Within our companion animal supply market, our principal customers are companion-pet and equine veterinarians, veterinary clinics, public and private institutions, and shelters. In our production animal supply market, our principal customers are large animal veterinarians, production animal operators and animal health product retailers. Consumer demand for alternative means of sourcing product through digital platforms is an evolving dynamic in our industry. We provide digital home delivery solutions to allow us to evolve with the market. Net sales and operating income were $4.0 billion and $127 million in fiscal 2023, respectively.

The following table sets forth the percentage of total sales by the principal categories of products and services offered to our animal health segment customers:

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Consumable	96 %	96 %	96 %
Equipment	3	3	3
Value-added services and other	1	1	1
	100 %	100 %	100 %

Patterson Animal Health obtains products from over 2,000 vendors globally. While Patterson Animal Health makes purchases from many vendors and there is generally more than one source of supply for most of the categories of products, the concentration of business with key vendors is considerable, as consolidation has increased among manufacturers. In fiscal 2023, 2022 and 2021, Patterson Animal Health's top 10 manufacturers comprised approximately 66%, 66% and 70% of the total cost of sales, respectively, and the single largest supplier comprised approximately 24%, 23% and 20% in of the total cost of sales 2023, 2022 and 2021, respectively.

Sales, Marketing and Distribution

During fiscal 2023, we sold products or services to over 100,000 customers who made one or more purchases during the year. Our customers include dentists, laboratories, institutions, other healthcare professionals, veterinarians, other animal health professionals, production animal operators and animal health product retailers. No single customer accounted for more than 10% of sales during fiscal 2023, and we are not dependent on any single customer or geographic group of customers.

We have offices throughout the U.S. and Canada so that we can provide a presence in the market and decision-making near the customer. Patterson Animal Health also has a central office in the U.K. Our offices, or sales branches, are staffed with a complete complement of our capabilities, including sales, customer service and technical service personnel, as well as a local manager who has decision-making authority with regard to customer-related transactions and issues.

A primary component of our value-added approach is our professional sales and support organization. Due to the highly-fragmented nature of the markets we serve, we believe that our unique combination of field-based and call-center sales and support teams is critical to reaching potential customers and providing a differentiated customer experience. Our sales representatives play an indispensable and critical role in managing a practice's supply chain and in introducing new products and technologies.

In the U.S. and Canada, customer service representatives in call centers work in tandem with our sales representatives, providing a dual coverage approach for individual customers. In addition to processing orders, customer service representatives are responsible for assisting customers with ordering, informing customers of monthly promotions, and responding to general inquiries. In the U.K., our customer service team is primarily responsible for handling customer inquiries and resolving issues.

To assist our customers with their purchasing decisions, we provide a multi-touchpoint shopping experience. From print to digital, this seamless experience is inclusive of products and services information. Patterson offers online and in-print showcases of our expansive merchandise and equipment offerings, including digital imaging and computer-aided design and computer-aided manufacturing ("CAD/CAM") technologies, hand-held and similar instruments, sundries, office design, e-services, repair and support assistance, as well as financial services. We also promote select products and services through publications, including *On Target* and *Advantage* in the U.S. and *Patterson Post* in Canada in our Dental segment, and *Insight* in the U.S. and *The Cube* in the U.K. in our Animal Health segment. Additional direct marketing tools that we utilize include customer loyalty programs, social media, and participation in trade shows.

We believe that responsive delivery of quality supplies and equipment is key to customer satisfaction. We ship consumable supplies from our strategically located fulfillment centers in the U.S. and Canada. In the U.K., orders are accepted in a centralized fulfillment center and shipped nationwide to one of our depots located throughout the country at which pre-packed orders are sorted by route for delivery to customers. Orders for consumable supplies can be placed through our sales representatives, customer service representatives or electronically 24 hours a day, seven days a week. Rapid and accurate order fulfillment is another principal component of our value-added approach.

In order to assure the availability of our broad product lines for prompt delivery to customers, we must maintain sufficient inventories at our fulfillment centers. Purchasing of consumables and standard equipment is centralized, and our purchasing department uses a real-time perpetual inventory system to manage inventory levels. Our inventory consists mostly of consumable supply items and pharmaceutical products.

Impacts of COVID-19

The COVID-19 pandemic had a significant impact on our businesses in fiscal 2021 as we implemented cost reduction measures in response to closures and other steps taken by governmental authorities. In response, management adapted our business practices with respect to employee travel, employee work locations, and cancellation of physical participation in meetings, events and conferences. Management also took proactive steps with respect to our liquidity position. Within our Dental segment, supply chain disruptions and an increased demand for PPE initially resulted in back orders of PPE, causing substantial price increases. We had to prepay suppliers in order to obtain PPE for resale to our customers, and as manufacturing caught up to increased demand for PPE, prices dropped, impacting our margins and requiring us to write down certain inventory.

In our markets of the U.S., Canada, and the UK, restrictive measures have now been lifted and the World Health Organization declared an end to the COVID-19 pandemic. Concerns remain that our markets could see a resurgence of COVID-19 cases or the emergence of new wide-spread public health outbreaks, triggering additional impacts on our businesses. There is continued uncertainty around the duration and ultimate impact of COVID-19 and other global health concerns.

Refer to Part I, Item 1A, "Risk Factors," and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," within this Annual Report for further information on the impacts to our business and results of operations, our dividends, liquidity and debt arrangements, and associated risks and uncertainties.

Geographic Information

For information on revenues and long-lived assets of our segments by geographic area, see Note 14 to the Consolidated Financial Statements.

Seasonality and Other Factors Affecting Our Business and Quarterly Results

Our business in general is not seasonal; however, there are some products that typically sell more often during the winter or summer season. In any given month, unusual weather patterns (e.g., unusually hot or cold weather) could impact the sales volumes of these products, either positively or negatively. In addition, we experience fluctuations in quarterly earnings. As a result, we may fail to meet or exceed the expectations of securities analysts and investors, which could cause our stock price to decline. Quarterly results may be materially adversely affected by a variety of factors, including:

- timing and amount of sales and marketing expenditures;
- timing of pricing changes offered by our suppliers;

- timing of the introduction of new products and services by our suppliers;
- changes in or availability of supplier contracts or rebate programs;
- supplier rebates based upon attaining certain growth goals;
- changes in the way suppliers introduce or deliver products to market;
- costs of developing new applications and services;
- our ability to correctly identify customer needs and preferences and predict future needs and preferences;
- uncertainties regarding potential significant breaches of data security or disruptions of our information technology systems;
- regulatory actions, or government regulation generally;
- loss of sales representatives;
- costs related to acquisitions and/or integrations of technologies or businesses;
- costs associated with our self-insured insurance programs;
- general market and economic conditions, as discussed in Item 1A: Risk Factors, including pandemic, macro-economic conditions, increased fuel and energy costs, consumer confidence, as well as conditions specific to the supply and distribution industry and related industries;
- our success in establishing or maintaining business relationships;
- difficulties of manufacturers in developing and manufacturing products;
- product demand and availability, or product recalls by manufacturers;
- exposure to product liability and other claims in the event that the use of the products we sell results in injury;
- increases in shipping costs or service issues with our third-party shippers;
- fluctuations in the value of foreign currencies;
- goodwill impairment;
- changes in interest rates;
- restructuring costs;
- the adoption or repeal of legislation;
- changes in accounting principles; and
- litigation or regulatory judgments, fines, forfeitures, penalties, equitable remedies, expenses or settlements.

Governmental Regulation

We strive to be compliant with the applicable laws, regulations and guidance described below, and believe we have effective compliance programs and other controls in place to ensure substantial compliance. However, compliance is not guaranteed either now or in the future, as certain laws, regulations and guidance may be subject to varying and evolving interpretations that could affect our ability to comply, as well as future changes, additions and enforcement approaches, including political changes. Additionally, our policies and procedures may not always protect us from reckless or criminal acts committed by our employees or our agents. When we discover situations of non-compliance we seek to remedy them and bring the affected area back into compliance.

President Biden's administration (the "Biden Administration") has indicated that it will be more aggressive in its pursuit of alleged violations of law, and has revoked certain guidance that would have limited governmental use of informal agency guidance to pursue potential violations, and has stated that it is more prepared to pursue individuals for corporate law violations, including an aggressive approach to anti-corruption activities. Changes to applicable laws, regulations and guidance described below, as well as related administrative or judicial interpretations, may require us to update or revise our operations, services, marketing practices, and compliance programs and controls, and may impose additional and unforeseen costs on us, pose new or previously immaterial risks to us, or may otherwise have a material adverse effect on our business, results of operations and financial condition.

Federal, state and certain foreign governments have also increased enforcement activity in the health care sector, particularly in areas of fraud and abuse, anti-bribery and corruption, controlled substances handling, medical device regulations and data privacy and security standards. Our businesses are generally subject to numerous laws and regulations that could impact our financial performance. Failure to comply with such laws or regulations could be punishable by criminal or civil sanctions, which could materially adversely affect our business.

Operating, Security and Licensure Standards

Our dental and animal health supply businesses involve the distribution, importation, exportation, marketing and sale of, and third party payment for, pharmaceuticals and medical devices, and in this regard, we are subject to extensive local, state, federal and foreign governmental laws and regulations applicable to the distribution of pharmaceuticals and medical devices.

U.S. Federal Agencies

Certain of our businesses are required to register for permits and/or licenses with, and comply with operating and security standards of, the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA"), the Environmental Protection Agency ("EPA"), the Food Safety Inspection Service ("FSIS"), the U.S. Drug Enforcement Administration ("DEA"), the Federal Trade Commission ("FTC"), and various state boards of pharmacy, state health departments and/or comparable state agencies as well as comparable foreign agencies, and certain accrediting bodies depending on the type of operations and location of product distribution, manufacturing or sale. These businesses include those that distribute, manufacture and/or repackage prescription pharmaceuticals and/or medical devices and/or HCT/P products, own pharmacy operations, or install, maintain or repair equipment.

FDA – the regulatory body that is responsible for the regulation of animal-health pharmaceuticals in the U.S. is the Center for Veterinary Medicine ("CVM") housed within the FDA.

- Generally, all animal-health pharmaceuticals are subject to pre-market review and must be shown to be safe, effective, and produced by a consistent method of manufacture as defined under the Federal Food, Drug and Cosmetic Act, as amended (the "FDC Act").
- If the drug is for food-producing animals, potential consequences for humans are also considered.
- Animal supplements generally are not required to obtain pre-market approval from the CVM, although they may be treated as food. Any substance that is added to, or is expected to become a component of, animal food must be used in accordance with food-additive regulations, unless it is generally recognized as safe, under the conditions of its intended use. Alternatively, the FDA may consider animal supplements to be drugs. The FDA has agreed to exercise enforcement discretion for such supplements if each such supplement meets certain conditions.
- Additionally, dental and medical devices we sell in the U.S. are generally classified by the FDA into a category that renders them subject to the same controls that apply to all medical devices, including regulations regarding alternation, misbranding, notification, record-keeping and good manufacturing practices.

USDA – the regulatory body in the U.S. for veterinary biologics, such as vaccines.

- The USDA's Center for Veterinary Biologics is responsible for the regulation of animal-health vaccines, including immunotherapeutics. Marketing of imported veterinary biological products in the U.S. requires a U.S. Veterinary Biological Product Permit. Veterinary biologics are subject to pre-market review and must be shown to be pure, safe, potent, and efficacious, as defined under the Virus Serum Toxin Act. The USDA requires post-licensing monitoring of these products.

EPA – the main regulatory body in the U.S. for veterinary pesticides is the EPA.

- The EPA's Office of Pesticide Programs is responsible for the regulation of pesticide products applied to animals.
- Animal-health pesticides are subject to pre-market review and must not cause "unreasonable adverse effects to man or the environment" as stated in the Federal Insecticide, Fungicide, and Rodenticide Act.
- Within the U.S., pesticide products that are approved by the EPA must also be approved by individual state pesticide authorities before distribution in that state. Post-approval monitoring of products is required, with reports provided to the EPA and some state regulatory agencies.

FSIS - the public health agency within the USDA.

- The FDA is authorized to determine the safety of substances (including "generally recognized as safe" substances, food additives and color additives), as well as prescribe their safe conditions of use. However,

although the FDA has the responsibility for determining the safety of substances, the FSIS still retains, under the tenets of the Federal Meat Inspection Act and the Poultry Products Inspection Act and their implementing regulations, the authority to determine whether new substances and new uses of previously approved substances are suitable for use in meat and poultry products.

DEA – under the Controlled Substances Act, distributors of controlled substances are required to obtain, and renew annually, registrations for their facilities from the DEA.

- Distributors are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling, and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times.
- Distributors are subject to inspection by the DEA.

FTC – the FTC regulates advertising pursuant to its authority to prevent "unfair or deceptive acts or practices in or affecting commerce" under the Federal Trade Commission Act.

- Advertising and promotion of animal-health products that are not subject to approval by the CVM may be challenged by the FTC, as well as by state attorneys general and by consumers under state consumer protection laws.
- The FTC will find an advertisement to be deceptive if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, the representation or omission is material, and if the advertiser does not possess and rely upon a reasonable basis, such as competent and reliable evidence, substantiating the claim.
- The FTC may address unfair or deceptive advertising practices through either an administrative adjudication or judicial enforcement action, including preliminary or permanent injunction.
- The FTC may also seek consumer redress from the advertiser in instances of dishonest or fraudulent conduct.

State Registrations – states may require registration of animal-drug distributors and wholesalers.

- Additional requirements may apply when the product is also a controlled substance. States work closely with the Association of American Feed Control Officials ("AAFCO") in their regulation of animal food.
- AAFCO's annual official publication contains model animal and pet-food labeling regulations that states may adopt.
- This publication is treated deferentially by the federal and state government agencies that regulate animal food. Many states require registration or licensing of animal-food distributors.
- States may also review and approve animal-food labels prior to sale of the product in their state.

We are also subject to foreign trade controls administered by certain U.S. government agencies, including the Bureau of Industry and Security within the Commerce Department, Customs and Border Protection within the Department of homeland Security and the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC).

The DEA, the FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our fulfillment centers, seize or order the recall of products and impose significant criminal, civil and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. Furthermore, compliance with legal requirements has required and may in the future require us to delay product release, sale or distribution, or institute voluntary recalls of, or other corrective action with respect to, products we sell, each of which could result in regulatory and enforcement actions, financial losses and potential reputational harm. Our customers are also subject to significant federal, state, local and foreign governmental regulation, which may affect our interactions with customers, including the design and functionality of the products we distribute.

Agencies Outside the U.S.

Since the U.K. formally left the EU on January 31, 2020, the Veterinary Medicines Directorate ("VMD") became the main regulatory body in the U.K. responsible for regulating and controlling veterinary pharmaceuticals. The U.K. and the EU reached a trade deal in December 2020, which went into effect in May 2021. The agreement includes regulatory and customs cooperation mechanisms, as well as provisions supporting open and fair competition. The Northern Ireland protocol, which is part of the trade deal, requires that VMD follow EU rules in Northern Ireland. Laws applying to the rest of the U.K. could now diverge but currently remain largely aligned.

U.S. Laws

Among the U.S. federal laws applicable to us are the Controlled Substances Act, the FDC Act, Section 361 of the Public Health Service Act, as well as laws regulating the billing of and reimbursement from government programs, such as Medicare and Medicaid, and from commercial payers. We are also subject to comparable foreign regulations.

The FDC Act, the Controlled Substances Act, their implementing regulations, and similar foreign laws generally regulate the introduction, manufacture, advertising, marketing and promotion, sampling, pricing and reimbursement, labeling, packaging, storage, handling, returning or recalling, reporting, and distribution of, and record keeping for, pharmaceuticals and medical devices shipped in interstate commerce, and states may similarly regulate such activities within the state. Furthermore, Section 361 of the Public Health Service Act, which provides authority to prevent the introduction, transmission, or spread of communicable diseases, serves as the legal basis for the FDA's regulation of human cells, tissues and cellular and tissue-based products, also known as "HCT/P products."

The federal Drug Quality and Security Act of 2013 brought about significant changes with respect to pharmaceutical supply chain requirements. Title II of this measure, known as the Drug Supply Chain Security Act ("DSCSA"), was first implemented in November 2014 and is being phased in over a period of 10 years. DSCSA is intended to build a national electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed in the U.S. The law's track and trace requirements applicable to manufacturers, wholesalers, third-party logistics providers (e.g., trading partners), repackagers and dispensers (e.g., pharmacies) of prescription drugs took effect in January 2015, and continues to be implemented. The DSCSA product tracing requirements replace the former FDA drug pedigree requirements and pre-empt certain state requirements that are inconsistent with, more stringent than, or in addition to, the DSCSA requirements.

The DSCSA also establishes certain requirements for the licensing and operation of prescription drug wholesalers and third party logistics providers ("3PLs"), and includes the eventual creation of national wholesaler and 3PL licenses in cases where states do not license such entities. The DSCSA requires that wholesalers and 3PLs distribute drugs in accordance with certain standards regarding the recordkeeping, storage and handling of prescription drugs. The DSCSA requires wholesalers and 3PLs to submit annual reports to the FDA, which include information regarding each state where the wholesaler or 3PL is licensed, the name and address of each facility and contact information. According to FDA guidance, states are pre-empted from imposing any licensing requirements that are inconsistent with, less stringent than, directly related to, or covered by the standards established by federal law in this area. Current state licensing requirements concerning wholesalers will remain in effect until the FDA issues new regulations as directed by the DSCSA.

The Food and Drug Administration Amendments Act of 2007 and the Food and Drug Administration Safety and Innovation Act of 2012 amended the FDC Act to require the FDA to promulgate regulations to implement a unique device identification ("UDI") system. The UDI rule phased in the implementation of the UDI regulations, generally beginning with the highest-risk devices (i.e., Class III medical devices) and ending with the lowest-risk devices. Most compliance dates were reached as of September 24, 2018, with a final set of requirements for low-risk devices being reached on September 24, 2022, which completed the phase in. However, in May 2021, the FDA issued an enforcement policy stating that it does not intend to object to the use of legacy identification numbers on device labels and packages for finished devices manufactured and labeled prior to September 24, 2023. The UDI regulations require "labelers" to include unique device identifiers ("UDIs"), with a content and format prescribed by the FDA and issued under a system operated by an FDA-accredited issuing agency, on the labels and packages of medical devices (including, but not limited to, certain software that qualifies as a medical device under FDA rules), and to directly mark certain devices with UDIs. The UDI regulations also require labelers to submit certain information concerning UDI-labeled devices to the FDA, much of which information is publicly available on an FDA database, the Global Unique Device Identification Database. On July 22, 2022, the FDA posted the final guidance regarding the Global Unique Device Identification Database called Unique Device Identification Policy Regarding

Compliance Dates for Class I and Unclassified Devices, Direct Marketing, and Global Unique Device Identification Database Requirements for Certain Devices. The UDI regulations and subsequent FDA guidance regarding the UDI requirements provide for certain exceptions, alternatives and time extensions. For example, the UDI regulations include a general exception for Class I devices exempt from the Quality System Regulation (other than record-keeping and complaint files). Regulated labelers include entities such as device manufacturers, repackagers, reprocessors and relabelers that cause a device's label to be applied or modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, and include certain of our businesses.

Under the Controlled Substances Act, as a distributor of controlled substances, we are required to obtain and renew annually registrations for our facilities from the DEA permitting us to handle controlled substances. We are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times. Non-controlled substances can also become subject to these controls. For example, law enforcement agencies are pressing for xylazine, which is an FDA-approved prescription veterinary tranquilizer found in certain analgesic products we distribute, to be listed as a federal controlled substance and several states, including Ohio, Pennsylvania, West Virginia and Florida, have already done so, which measures are likely to increase our cost of distributing such products. There have also been increasing efforts by various levels of government globally to regulate the pharmaceutical distribution system in order to prevent the introduction of counterfeit, adulterated or misbranded pharmaceuticals into the distribution system.

In addition, Section 301 of the National Organ Transplant Act, and a number of comparable state laws, impose civil and/or criminal penalties for the transfer of certain human tissue (for example, human bone products) for valuable consideration, while generally permitting payments for the reasonable costs incurred in procuring, processing, storing and distributing that tissue. We are also subject to foreign government regulation of such products.

Certain of our businesses are subject to various additional federal, state, local and foreign laws and regulations, including with respect to the sale, transportation, storage, handling and disposal of hazardous or potentially hazardous substances, and safe working conditions. In addition, certain of our businesses must operate in compliance with a variety of burdensome and complex billing and record keeping requirements in order to substantiate claims for payment under federal, state and commercial healthcare reimbursement programs.

Certain of our businesses also maintain contracts with governmental agencies and are subject to certain regulatory requirements specific to government contractors.

As disclosed in our prior periodic reports, our subsidiary Animal Health International was the subject of an investigation by the U.S. Attorney's Office for the Western District of Virginia, which resulted in Animal Health International pleading guilty to a strict-liability misdemeanor offense in connection with its failure to comply with federal law relating to the sales of prescription animal health products, and a total criminal fine and forfeiture of $52.8 million. In addition, Animal Health International and Patterson entered into a non-prosecution agreement for other non-compliant licensing, dispensing, distribution and related sales processes disclosed during the investigation and committed to undertake additional compliance program enhancements and provide compliance certifications through our reporting for fiscal 2023. This matter may continue to divert management's attention and cause us to suffer reputational harm. We also may be subject to other fines or penalties, equitable remedies (including but not limited to the suspension, revocation or non-renewal of licenses) and litigation. The occurrence of any of these events could adversely affect our business, results of operations and financial condition.

Other Regulations

Veterinary compounding pharmacies must comply with state and federal laws that govern the relationship between pharmacies and referral sources. The U.S. Federal Anti-Kickback Statute ("AKS") imposes criminal penalties against individuals and entities that pay or receive remuneration in return for referring an individual for service paid under a federal health care program. Veterinary compounding pharmacies have historically avoided scrutiny under the AKS because no federal programs are involved in veterinary compounding funding. However, most states have enacted statutes and regulations that mirror the AKS and, in some cases, are even broader than the AKS.

Various states have enacted business and insurance regulations prohibiting referral arrangements that result in the offer or acceptance of any rebate, refund, commission, discount or other consideration as compensation or inducement for referring patients, clients or customers. These regulations often encompass all health-care related professions, including pharmacies and veterinary practices.

Additionally, the promotion of regulated animal health products is controlled by regulations in many countries. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and endorsed by the applicable agency.

Antitrust and Consumer Protection

The U.S. federal government, most U.S. states and many foreign countries have antitrust laws that prohibit certain types of conduct deemed to be anti-competitive, as well as consumer protection laws that seek to protect consumers from improper business practices. At the U.S. federal level, the Federal Trade Commission oversees enforcement of these types of laws, and states have similar government agencies. Violations of antitrust or consumer protection laws may result in various sanctions, including criminal and civil penalties. Private plaintiffs also may bring, and have brought, civil lawsuits against us in the U.S. for alleged antitrust violations, including claims for treble damages. The Biden Administration has indicated increased antitrust enforcement and has been more aggressive in enforcement actions, including investigations and challenging restrictive contractual terms that it believes harm workers and competition.

Health Care Fraud

Certain of our businesses are subject to federal and state (and similar foreign) health care fraud and abuse, referral and reimbursement laws and regulations with respect to their operations. These laws and regulations govern different interactions, including but not limited to, those:

- prohibiting improper influence of or payments to healthcare professionals and government officials;
- setting out rules for when and how to engage healthcare professionals as vendors;
- requiring price reporting;
- requiring marketing of products within regulatory approval (i.e., on label);
- regulating the import and export of products;
- affecting the operation of our facilities and our distribution of products; and
- requiring disclosure of payments to healthcare professionals and entities.

Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by federal, state and other health care payers and programs. Several states apply their false claims and anti-kickback laws to all payers, including goods and services paid for directly by consumers. Certain additional state and federal laws, such as the federal Physician Self-Referral Law, commonly known as the "Stark Law," prohibit physicians and other health professionals from referring a patient to an entity with which the physician (or family member) has a financial relationship, for the furnishing of certain designated health services (for example, durable medical equipment and medical supplies), unless an exception applies. Violations of anti-kickback laws or the Stark Law may be enforced as violations of the federal False Claims Act.

The fraud and abuse laws and regulations have been subject to heightened enforcement activity over the past few years, and significant enforcement activity has been the result of "relators," who serve as whistleblowers by filing complaints in the name of the U.S. (and, if applicable, particular states) under applicable false claim laws. Under the federal False Claims Act, relators can be entitled to receive up to 30% of the total recoveries. Penalties under fraud and abuse laws may be severe, including treble damages and substantial civil penalties under the federal False Claims Act, as well as potential loss of licenses and the ability to participate in federal and state health care programs, criminal penalties, or imposition of a corporate integrity agreement or corporate compliance monitor which could have a material adverse effect on our business. Also, these measures may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal False Claims Act penalties, as well as other fraud and abuse laws. With respect to measures of this type, the U.S. government (among others) has expressed concerns about financial relationships between suppliers on the one

Animal Health INTERNATIONAL

May 29, 2013

California State Board of Pharmcy
Attn: Jennifer Sevilla
1625 North Market Blvd, Suite N219
Sacramento, CA 95834-1924

RE: File No: CI 2011 52457 / CI 2012 56535

Ms. Sevilla:

In response to the aforementioned citations, please find the payment in the amount of $500 in the settlement of CI 2012 56535.

Please accept the enclosed payment from Animal Health International on Ms. Espinola's behalf, as the alleged violation occurred while she was acting as an employee of Animal Health International.

I trust this will satisfy your request, but please feel free to contact me at the number below if you have any questions or if I can be of any further assistance.

Regards,

Marcus Prochazka
Regulatory Manager
Animal Health International, Inc.
P.O. Box 1240
Greeley, CO 80632
970.378.2012 phone
970.346.2312 fax
marcus.prochazka@animalhealthinternational.com

Vendor No: 338307
Vendor Name: CALIFORNIA BOARD OF PHARMACY

Invoice Number	Invoice Date	Invoice Comments	Gross Amount	Discount	Net Amount
052213CR	05/22/2013		500.00	0.00	500.00
		Check Total............................			$ 500.00

DETACH FROM CHECK AND KEEP FOR YOUR RECORDS

THIS CHECK HAS A COLORED FACE ON WHITE STOCK AND AN ARTIFICIAL WATERMARK ON THE BACK.

Animal Health INTERNATIONAL

PO BOX 1360 • GREELEY, CO 80632 • (970) 353-2600

usbank
US Bank
235 First Street
Havre MT 59501-3526

93-445
929

Check No: 10125260
Check Date: 05/29/2013

PAY TO THE ORDER OF CALIFORNIA BOARD OF PHARMACY $500.00

FIVE HUNDRED & 00/100 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DOLLARS

CALIFORNIA BOARD OF PHARMACY
1625 NORTH MARKET BLVD #N219
SACRAMENTO CA 95834-1924

[redacted]

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number: CI 2012 56535
Name, License No: GRACIE MARIE ESPINOLA , EXV 20090

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1	Minimum standards for veterinary food-animal drug retailers	$500.00

CONDUCT:

Gracie Espinola (EXV 20090) was not in compliance with California Code of Regulations, title 16, section 1780.1 (h)(9), which requires labels affixed to a veterinary food-animal drug dispensed to Business and Professions Code section 4041 shall contain the withdrawal time. Specifically, on 1/3/2012, while working at AHI-West (located at 8711 West Doe Avenue, Suite A, Visalia, CA 932910), veterinary retailer designated representative Gracie Espinola furnished RX# BW1728 (Polyflex 25gm) for client JVD with an incorrect label associated with the withdrawal time (missing withhold time of 2 days for milk; label on bottle indicated only withhold time of 6 days for meat). This is a violation of pharmacy law.

CITATION ISSUED ON: April 18, 2013 | **TOTAL AMOUNT OF FINE(S): $500.00**

PAYMENT OF FINE(S) DUE BY: May 18, 2013

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement, a fine, and AHI paid $41,250.

b. On April 18, 2013, Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food-Animal Drug Retailer license was cited by the California Board of Pharmacy for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, Animal Health International, Inc.'s (AHI) Salina, Kansas facility was issued a drug distributor license by the Missouri Division of Professional Regulation. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license was cited by the California Board of Pharmacy for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failure to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no allegations of misconduct beyond the conduct in Arkansas which led to the non-disciplinary order and fine.

f. In March 2017, Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license was issued a letter of admonishment by the Colorado Board of Pharmacy following allegations that it failed to timely submit an application to the Board detailing a change in designated representative.AHI was required to pay costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce veterinary prescription drugs that were misbranded to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine in the amount of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Boaz, Alabama wholesale drug distributor license.

i. On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license (#PH32369). This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/4/2013	3/5/2013	FL	Tallahassee	Leon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2012-026145	Florida Department of Business and Professional Regulation (DBPR)

Reason/Charge
Violations of Sections 499.005(22) and 499.005(2)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc

Provide explanation below:

On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement, a fine, and AHI paid $41,250.

Kelly Karas

Original Signature (electronic, copies or stamps not accepted)

11/17/23

Date

FILED
Department of Business and Professional Regulation
Deputy Agency Clerk
CLERK Brandon Nichols
Date 3/5/2013
File # 2013-01148

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULAT

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v.

ANIMAL HEALTH INTERNATIONAL, INC.,

Respondent.
_____/

CASE NOs.: 2012-026145
2012-026174
2012-040970
2012-040997

FINAL ORDER

The Department of Business & Professional Regulation (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Animal Health International, Inc., (Respondent) and the Department, attached hereto and incorporated by reference. This final order and settlement agreement are to resolve alleged violations of Section 499.005(22), Florida Statutes, (2010-2012), failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required; and Section 499.005(2), Florida Statutes (2010-2012), the adulteration or misbranding of any drug, device or cosmetic.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 4th day of March, 2013 in Tallahassee, Florida.

KEN LAWSON, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Reginald D. Dixon
Executive Director
Drugs, Devices and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been served by regular U.S. Mail this 5th day of March, 2013, to: Animal Health International, Inc.; Attention Lyndee J. Collins, 343 West Main Street, Mayo, Florida 32066.

Brandon M. Nichols
Agency Clerk's Office

cc: Kathryn E. Price
Chief Attorney
Drugs, Devices and Cosmetics
1940 N. Monroe Street
Tallahassee, Florida 32399-1047

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v.

Case Nos.: 2012-026145
2012-026174
2012-040970
2012-040997

ANIMAL HEALTH INTERNATIONAL, INC.,

Respondent.
_____/

RECEIVED
MAR 04 2013
Drugs, Devices and Cosmetics

SETTLEMENT AGREEMENT

Pursuant to Section 120.57, Florida Statutes, the above named parties hereby enter into this settlement as disposition of the attached Amended Notice of Violation, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1. Animal Health International, Inc. (hereinafter "Animal Health") was issued the attached Amended Notice of Violation (hereafter, "Notice of Violation") for its non-compliance with veterinary prescription drug wholesale distributor permit requirements of the Department.

2. The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 499.001, Florida Statutes.

CONCLUSIONS OF LAW

3. Animal Health, by and through its undersigned officer, admits that it is subject to the provisions of Chapter 499, Florida Statutes, and to the jurisdiction of the Department.

4. Animal Health admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes, but Animal health neither admits nor denies those findings.

SETTLEMENT

5. Animal Health agrees to immediately cease any practices that are in violation of Chapter 499, Florida Statutes.

6. Animal Health agrees to pay a fine of **Forty-one Thousand, Two Hundred Fifty Dollars ($41,250.00)**. Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, C/O Janetta Sampson, Drugs, Devices and Cosmetics, 1940 North Monroe Street, Suite 26A, Tallahassee, FL 32399-1047. Respondent acknowledges that payment is enclosed with this agreement The payment of the settlement amount and execution of this agreement by Respondent are absolute conditions precedent to Petitioner's execution of this agreement. By its acceptance of Respondent's payment and execution of this agreement, Petitioner agrees that all allegations of noncompliance alleged in the Notice of Violation shall be fully, finally, and conclusively resolved.

7. Animal Health affirms that the alleged violations cited in the Notice of Violation have been corrected

8 Animal Health affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted pursuant thereto.

9 It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

10. Animal Health expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of this Settlement Agreement and the final order in which the agreement is incorporated.

11. Each party waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

ANIMAL HEALTH INTERNATIONAL, INC.

By: _____

Name: David R. Wagley

Title: Executive VP and CFO

Date: 02/26/2013

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Name: REGINALD D. DIXON

Title: DIRECTOR

Date: 3/4/13

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/18/2013		CA	Sacramento	Sacramento
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CI 2012 56535		California State Board of Pharmacy		
Reason/Charge				
Violation of California Code of Regulations, title 16, section 1780.1 (h)(9)				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Gracie Marie Espinola		N/A		
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On April 18, 2013, Animal Health International, Inc.'s (AHI) Visalia, California Veterinary FoodAnimal Drug Retailer license was cited by the California Board of Pharmacy for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

Kelly Kane
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

Regulatory Licensing Mgr

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 18, 2013

DATED MATERIAL ENCLOSED

GRACIE MARIE ESPINOLA
[redacted] WEST OWENS AVE
TULARE, CA 93274

RE: CI 2012 56535
GRACIE MARIE ESPINOLA
EXV 20090

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- May 18, 2013: Unless the Citation is contested payment of fine(s) must be received by the Board.
- May 02, 2013: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 18, 2013: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Jennifer Sevilla, Enforcement Analyst at (916) 574-7925.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/18/2013	6/18/2013	MO	Jefferson City	Cole

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2012-007179	Missouri Board of Pharmacy

Reason/Charge
Violations of Section 324.038, RSMo; Section 338.055.1 and .2(6)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Icn.

Provide explanation below:

On June 18, 2013, Animal Health International, Inc.'s (AHI) Salina, Kansas facility was issued a drug distributor license by the Missouri Division of Professional Regulation. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

Kelley Karr
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

Regulatory Licensing Mgr

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grimston
Executive Director
www.pr.mo.gov/pharmacists
e-mail: MissouriBOP@pr.mo.gov

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7196 9008 9040 1809 0513

June 20, 2013

Stephen B. Leinenbach
Senior VP of Operations
Animal Health International, Inc.
1449A W. Old Highway 40
Salina, KS 67401

Dear Mr. Leinenbach:

I am writing to you as a representative of the Missouri Board of Pharmacy ("Board"). At the April 2013 meeting, the Board reviewed your application for licensure as a drug distributor in Missouri for your facility located at 1449A W. Old Highway 40, Salina, Kansas.

After careful consideration, it was the Board's decision to issue Animal Health International, Inc. a restricted drug distributor license pursuant to Section 324.038, RSMo, based on violation of Section 338.055.1 and .2(6), RSMo. A copy of the Board's Order containing the restrictions that have been imposed on your license is enclosed. Your permanent Missouri drug distributor license, numbered 2013019603, that was issued June 18, 2013, with restrictions is enclosed. Please review the enclosed Order carefully. **It is your responsibility to comply with all terms of this Order**. If you have questions about any portion of the terms and conditions, contact this office.

Enclosed are two copies of the Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Order. The first report will be due July 1 and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is available on our website, www.pr.mo.gov/pharmacists, click Applications and Forms, Miscellaneous.

If you wish to contest the Board's decision, you must file a written complaint with the Administrative Hearing Commission within thirty (30) days following delivery or certified mailing of this letter and Order. The written request should be addressed to the Administrative Hearing

Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30)-day period, the right to seek review of the Board's decision shall will be considered waived.

Sincerely,

Tammy Siebert

TAMMY SIEBERT
EXECUTIVE I

Enclosures

cc: Jolene Goddard, Manager-in-Charge

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	Case #2012-007179

ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ANIMAL HEALTH INTERNATIONAL, INC. A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2013019603, to Animal Health International, Inc. ("Animal Health") pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Animal Health may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Animal Health. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Animal Health's license as a drug distributor. Should Animal Health file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Animal Health filed an application for a drug distributor license with the Board on November 5, 2012. This probated drug distributor license is for the facility owned by Animal Health at 1449A N. Old Highway 40, Salina, Kansas 67401. The Board had previously issued Walco International, Inc. a drug distributor license number 2003031150, for this location.

3. Animal Health shipped legend drugs from its current location from June 11, 2011, through January 22, 2013, without being licensed to do so. Animal Health's records reflect that it delivered at least 869 orders of legend drugs within Missouri without a valid drug distributor license.

4. Based on information received by the Board, pursuant to Section 338.055, RSMo, the Board concluded Animal Health engaged in conduct which would be grounds for denying Animal Health a license, or if currently licensed by the Board, disciplinary action by the Board against its drug distributor license.

CONCLUSIONS OF LAW

5. Animal Health's conduct as alleged above is cause for the Board to deny Animal Health a license to be a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

> 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.
>
> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

6. Section 324.038, RSMo, provides in pertinent part:

> 1. Whenever a board within the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

7. The Board hereby issues this ORDER in lieu of denial of Animal Health's request for a drug distributor license in Missouri pursuant to Section 324.038, RSMo.

8. Pursuant to the provisions of Section 324.038, RSMo, the Board hereby issues drug distributor license number 2013019603 to Animal Health in lieu of denial of Animal Health's request for a license to practice as a drug distributor in Missouri. License number 2013019603 is issued subject to the terms and conditions set forth herein below.

ORDER

Based on the foregoing and in lieu of denying Animal Health International, Inc., a drug distributor license, the Board hereby issues Animal Health International, Inc. a license subject to PROBATION for two (2) years (hereinafter "disciplinary period"). The terms of the disciplinary period shall be:

1. Respondent shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

4. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not he/she has complied with all terms and conditions of his/her disciplinary order.

5. Respondent shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

6. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order.

7. The Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

8. Upon the expiration of the disciplinary period, Animal Health's license as a drug distributor shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Animal Health has violated any term or

condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Animal Health 's drug distributor license.

9. No order shall be entered by the Board pursuant to the preceding paragraph of this Order without notice and an opportunity for a hearing before the Board in accordance with provisions of Chapter 536, RSMo.

10. If the Board determines that Animal Health has violated a term or condition of this Order, which violation would be actionable in a proceeding before the Administrative Hearing Commission or the Circuit Court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

SO ORDERED this 18th day of June, 2013

MISSOURI BOARD OF PHARMACY

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

MAILING ADDRESS:
MISSOURI BOARD OF PHARMACY
P.O. BOX 625
JEFFERSON CITY, MO 65102
(573) 751-9056
(573) 526-3464 (FAX)
E-MAIL: COMPLIANCE@PR.MO.GOV
DELIVERY ADDRESS:
3605 MISSOURI BOULEVARD
JEFFERSON CITY, MO 65109

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION

PHARMACY AND DRUG DISTRIBUTOR REPORT OF DISCIPLINE COMPLIANCE

INSTRUCTIONS:

1. This form MUST be completed/signed by the sole proprietor, partner or corporate officer of the pharmacy/drug distributor.
2. Fill in all blanks and answer all questions completely and accurately.

LICENSEE INFORMATION

PHARMACY/DRUG DISTRIBUTOR NAME	LICENSE NO.	DATE
PHARMACY/DRUG DISTRIBUTOR ADDRESS (STREET, CITY, STATE ZIP CODE)		CURRENT TELEPHONE NUMBER
PHARMACY/DRUG DISTRIBUTOR E-MAIL ADDRESS		ALTERNATE TELEPHONE NUMBER
PHARMACIST/MANAGER-IN-CHARGE NAME		LICENSE NO. (IF APPLICABLE)

MISSOURI LICENSE STATUS IS
☐ ACTIVE ☐ INACTIVE ☐ EXPIRED

IF "EXPIRED," DATE LICENSE EXPIRED

HAS THIS PHARMACY/DRUG DISTRIBUTOR CHANGED LOCATIONS IN THE PAST SIX (6) MONTHS?
☐ YES ☐ NO

IF YES, WAS THE CHANGE OF LOCATION REPORTED TO THE BOARD OFFICE?
☐ YES ☐ NO

HAS THIS PHARMACY/DRUG DISTRIBUTOR FILED ANY DEA OR BNDD LOSS REPORTS IN THE PAST SIX (6) MONTHS?
☐ YES ☐ NO (IF YES, ATTACH COPIES TO THIS REPORT)

THE FOLLOWING IS A CURRENT LIST OF PARTNERS/CORPORATE OFFICERS OF THIS PHARMACY/DRUG DISTRIBUTOR (ATTACH SEPARATE SHEET IF NECESSARY)

NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE

THE FOLLOWING IS A LIST OF ALL FULL-TIME AND PART-TIME LICENSED/REGISTERED PHARMACISTS, INTERNS, TECHNICIANS PERFORMING DUTIES AT THIS PHARMACY/DRUG DISTRIBUTOR (ATTACH SEPARATE SHEET IF NECESSARY)

NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION

COMPLIANCE STATEMENT

DATES OF MISSOURI DISCIPLINE

PROBATION _____ TO _____

HAVE YOU REVIEWED THE PHARMACY/DRUG DISTRIBUTOR'S DISCIPLINARY ORDER/SETTLEMENT AGREEMENT IN THE LAST SIX (6) MONTHS?

☐ YES ☐ NO

I/WE HAVE DONE THE FOLLOWING TO COMPLY WITH EACH REQUIREMENT OF THE DISCIPLINARY ORDER/SETTLEMENT AGREEMENT. (ATTACH SEPARATE SHEET IF NECESSARY)

CONSULTANT INFORMATION

If a consultant is a requirement of your discipline, answer the following.

NAME OF CONSULTANT	CONSULTANT TELEPHONE NUMBER

ADDRESS OF CONSULTANT

DATE OF LAST VISIT	DATE OF NEXT VISIT	CONSULTANT E-MAIL ADDRESS

LIST ANY CHANGE YOU HAVE MADE TO YOUR OPERATION BASED ON YOUR CONSULTANT'S LAST REPORT (ATTACH ADDITIONAL SHEETS IF NECESSARY).

By my signature below, I hereby attest that I am a partner, corporate officer, or the sole proprietor of the pharmacy/drug distributor named in this compliance report, and the report has been completed knowingly, truthfully and completely, without omissions. I understand that this pharmacy/drug distributor must comply with federal and state laws and regulations, including that the facility shall maintain a pharmacist/manager-in-charge for the facility and such pharmacy/drug distributor shall be conducted and operated in full compliance with state and federal laws and regulations. All the information contained in the report and any attachments hereto are true and correct to my best knowledge and belief. I understand that any false statement or material omission may result in discipline or further penalty under state law. I hereby certify under the penalty of perjury that the above statement, as well as all information provided herein are true and correct.

SIGNATURE OF SOLE PROPRIETOR, PARTNER OR CORPORATE OFFICER	DATE

PRINT NAME	TITLE

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Kathleen (Katie) Steele Danner, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists
email: MissouriBOP@pr.mo.gov

July 7, 2015

Stephen Leinenbach
Senior VP of Operations
Animal Health International, Inc.
PO Box 1240
Greeley CO 80632

Dear Mr. Leinenbach:

This is official notification that Animal Health International Inc., permit #2013019603 has completed the terms of probation with the Missouri Board of Pharmacy as of June 17, 2015.

If you have any questions, or if we can be of assistance in the future, feel free to contact this office. Thank you for complying.

Sincerely,

Jennifer Luebbert
Compliance Coordinator
Missouri Board of Pharmacy

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/30/2013	8/30/2013	CA	Sacramento	Sacramento

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2013 58076	California Board of Pharmacy

Reason/Charge
Not in compliance with CCR, Title 16, § 1780 and Bus and Prof Code 4053

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On August 30, 2013, Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license was cited by the California Board of Pharmacy for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failure to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

0971

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2013 58076	JOSEPH E SHACKELFORD , EXV 16742

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1 subd. (d)	Only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian	$1,000.00
CCR, Title 16, § 1780.1 subd. (h)	Labels affixed to a veterinary food-animal drug...label requirements	$500.00
Bus. & Prof. Code § 4053 subd. (d)	Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs	$1,000.00

CONDUCT:

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with California Code of Regulations, section 1780.1(d) which states only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian. Specifically, on 3/27/12, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were receiving oral orders from veterinarians. This was a violation of pharmacy law.

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with California Code of Regulations, section 1780.1(h)(2)(15) which states labels affixed to a veterinary food-animal drug shall contain the manufacturer of the drug and the manufacturer's expiration date. Specifically, on 3/27/23, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was noted the manufacturer of the drug or the expiration date was not indicated on the prescription labels. This was a violation of pharmacy law.

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with Business and Professions Code, Section 4053(d) which states only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs. Specifically, on 3/27/12, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were preparing and affixing the labels for food-animal drugs. This was a violation of pharmacy law.

CITATION ISSUED ON: August 30, 2013 TOTAL AMOUNT OF FINE(S): $2,500.00

PAYMENT OF FINE(S) DUE BY: September 29, 2013

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2013 58075	MARK ALDAX , EXV 15005

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)	Furnishing dangerous drugs without a prescription	$500.00

CONDUCT:

Vet Retailer Exemptee, Mark Aldax was not in compliance with Business and Professions Code, section 4059(a) which states a person cannot furnish any dangerous drug, except upon the prescription of a physician, dentist, veterinarian. Specifically, on 6/20/12, 7/26/12, and 12/19/12 Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Mark Aldax, EXV 15005, was vet retailer exemptee, furnished several different dangerous drugs including long acting antibiotics without authorization from Dr. Grant Miller. This was a violation of pharmacy law.

CITATION ISSUED ON: August 30, 2013 **TOTAL AMOUNT OF FINE(S): $500.00**

PAYMENT OF FINE(S) DUE BY: September 29, 2013

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2012 53842	ANIMAL HEALTH INTERNATIONAL INC, VET 144

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1 subd. (d)	Only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian	$1,000.00
CCR, Title 16, § 1780.1 subd. (h)	Labels affixed to a veterinary food-animal drug...label requirements	$500.00
Bus. & Prof. Code § 4059 subd. (a)	Furnishing dangerous drugs without a prescription	$1,000.00
Bus. & Prof. Code § 4053 subd. (d)	Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs	$1,000.00

CONDUCT:

Animal Health International (Vet 144) was not in compliance with California Code of Regulations, section 1780.1(d) which states only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were receiving oral orders from veterinarians. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with California Code of Regulations, section 1780.1(h)(2)(15) which states labels affixed to a veterinary food-animal drug shall contain the manufacturer of the drug and the manufacturer's expiration date. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, did not have the manufacturer of the drug or the expiration date indicated on the prescription labels. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with Business and Professions Code, section 4059(a) which states a person cannot furnish any dangerous drug, except upon the prescription of a physician, dentist, veterinarian. Specifically, on 6/20/12, 7/26/12, and 12/19/12 Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, furnished several dangerous drugs including long acting antibiotics without authorization from Dr. Grant Miller. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with Business and Professions Code, Section 4053(d) which states only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were preparing and affixing the labels for food-animal drugs. This was a violation of pharmacy law. 0975

CITATION ISSUED ON: August 30, 2013 **TOTAL AMOUNT OF FINE(S): $3,500.00**

PAYMENT OF FINE(S) DUE BY: September 29, 2013

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/13/2017	3/13/2017	AL	Birmingham	Jefferson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
17-L-0003		Alabama Board of Pharmacy		
Reason/Charge				
Violation of Alabama Pharmacy Practice Act				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Animal Health International, Inc.		N/A		
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no allegations of misconduct beyond the conduct in Arkansas which led to the non-disciplinary order and fine.

Kelley Kare
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
ANIMAL HEALTH INTERNATIONAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Non-Resident Pharmacy Permit Number: 114325	)	**CASE NO: 17-L-0003**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. ("Animal Health") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Animal Health through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Animal Health has violated the provisions of law based upon the conduct set out in Counts One and Two of the Statement. Count Three of the Statement shall be dismissed with prejudice.

2. Animal Health shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Animal Health expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform

Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Animal Health International, Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Animal Health hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Animal Health acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Animal Health's permit, including, but not limited to revocation.

6. Animal Health acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Animal Health acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 3rd of March, 2017.

ANIMAL HEALTH INTERNATIONAL, INC.

BY: _____

ITS: VP, Regulatory Affairs

_____
Christopher Bottcher, attorney for Animal Health International, Inc.

DONE this the 13th of March, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Buddy Bunch, R.Ph., President

By: _____
James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/13/2017	3/20/2017	CO		Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2016-4043	Colorado Board of Pharmacy

Reason/Charge
Violation of §12-42.5-123(1)(l)-(III), C.R.S.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

In March 2017, Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license was issued a letter of admonishment by the Colorado Board of Pharmacy following allegations that it failed to timely submit an application to the Board detailing a change in designated representative.AHI was required to pay costs associated with the Board's order.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2016-4043

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF ANIMAL HEALTH INTERNATIONAL, INC., REGISTRATION NO. WHI 6020,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Animal Health International, Inc. ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2016-4043, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 8, 2006, being issued registration number WHI 6020, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 620 "O" Street, Greeley, CO 80632.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, approximately 240 days transpired between December 1, 2015, the date the previous designated representative ceased the position, and August 4, 2016, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet admits that its conduct, as set forth above, constitutes a violation of §12-42.5-123(1)(c)(I)-(III), C.R.S., and Rules 15.01.11(b) and 15.01.14(c) and provides grounds for disciplinary action against Respondent Outlet's Colorado registration as a wholesaler.

TERMS OF DISCIPLINE

8. **Letter of Admonition.** This Final Agency Order shall constitute a Letter of Admonition as set forth in §12-42.5-124(6)(b) and (c), C.R.S. The Board hereby admonishes Respondent Outlet for the acts and omissions described in paragraphs 5-7 above.

9. **Waiver of Right to Contest.** By entering into this Final Agency Order, Respondent Outlet agrees to waive the right provided by §12-42.5-124(6)(b) and (c), C.R.S., to contest this Letter of Admonition.

10. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges.

    c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

17. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

_____ Dated: 3/20/2017
Authorized Representative / Title

Subscribed and sworn to before me in the County of Weld, State of Colorado, this 20th day of March, 2017, by David R. Wagley, authorized representative of Animal Health International, Inc.

My commission expires: Jan 5, 2019 _____
Notary Public

ISABELLA NOVAK
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID # 20154000145
MY COMMISSION EXPIRES JANUARY 05, 2019

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 23rd day of March, 2017.

State Board of Pharmacy

BY: _____
Chris Gassen
Interim Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 23rd day of March 2017, addressed as follows:

By electronic mail to Respondent:
Animal Health International, Inc.
Attn: Marcus Prochazka, Regulatory Mngr.
620 "O" Street
Greeley, CO 80632
Email: Marcus.Prochazka@animalhealthinternational.com

Agent of the Board

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/14/2020		VA	Abingdon	Washington
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
DVAW120CR00007-001	United States District Court, Western District of Virginia Abingdon			
Reason/Charge				
Violation of Title 21, US Code, Sections 331(a), 333(a)(1), and (352)(f)(l)				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Animal Health International, Inc.	N/A			
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce veterinary prescription drugs that were misbranded to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

UNITED STATES DISTRICT COURT
Western District of Virginia

UNITED STATES OF AMERICA
V.
ANIMAL HEALTH INTERNATIONAL, INC.

JUDGMENT IN A CRIMINAL CASE
(For Organizational Defendants)
CASE NUMBER: DVAW120CR000007-001
CASE NUMBER:
Amy J. Conway-Hatcher, Kyle A. Clark
Defendant Organization's Attorney

THE DEFENDANT ORGANIZATION:

☒ pleaded guilty to count(s) Count 1 of Information

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

The organizational defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
21 U.S.C. § 331(a), 333(a)(1), and 352(f)(1)	Introduction of Misbranded Drugs into Interstate Commerce	4/2015	1

The defendant organization is sentenced as provided in pages 2 through 8 of this judgment.

☐ The defendant organization has been found not guilty on count(s) _____

☐ Count(s) _____ ☐ is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant organization must notify the United States attorney for this district within 30 days of any change of name, principal business address, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant organization must notify the court and United States attorney of material changes in economic circumstances.

Defendant Organization's
Federal Employer I.D. No.: 84-0575063

Defendant Organization's Principal Business Address:

822 7th Street
Suite 610
Greeley, CO 80631

Defendant Organization's Mailing Address:

822 7th Street
Suite 610
Greeley, CO 80631

May 4, 2020
Date of Imposition of Judgment

James P. Jones
Signature of Judge

James P. Jones, United States District Judge
Name and Title of Judge

5/4/2020
Date

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

PROBATION

The defendant organization is hereby sentenced to probation for a term of :

One (1) year.

The defendant organization shall not commit another federal, state or local crime.

If this judgment imposes a fine or a restitution obligation, it is a condition of probation that the defendant organization pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant organization must comply with the standard conditions that have been adopted by this court as well as any additional conditions on the attached page (if indicated below).

STANDARD CONDITIONS OF SUPERVISION

1) within thirty days from the date of this judgment, the defendant organization shall designate an official of the organization to act as the organization's representative and to be the primary contact with the probation officer;

2) the defendant organization shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;

3) the defendant organization shall notify the probation officer ten days prior to any change in principal business or mailing address;

4) the defendant organization shall permit a probation officer to visit the organization at any of its operating business sites;

5) the defendant organization shall notify the probation officer within seventy-two hours of any criminal prosecution, major civil litigation, or administrative proceeding against the organization;

6) the defendant organization shall not dissolve, change its name, or change the name under which it does business unless this judgment and all criminal monetary penalties imposed by this court are either fully satisfied or are equally enforceable against the defendant's successors or assignees; and

7) the defendant organization shall not waste, nor without permission of the probation officer, sell, assign, or transfer assets.

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

SPECIAL CONDITIONS OF SUPERVISION

While on probation, the defendant:

(1) Must comply with the requirements contained in the Plea Agreement and the Non-Prosecution Agreement of Defendant's parent corporation.

AO 245E (Rev. 12/03 - VAW Additions 3/04) Judgment in a Criminal Case for Organizational Defendants
Sheet 3 - Criminal Monetary Penalties

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

CRIMINAL MONETARY PENALTIES

The defendant organization must pay the following total criminal monetary penalties under the schedule of payments on Sheet 4.

	Assessment	Fine	Restitution
TOTALS	$ 125.00	$ 5,000,000.00	$

☐ The determination of restitution is deferred until _____ . An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant organization shall make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant organization makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS	$0.00	$0.00

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant organization shall pay interest on restitution or a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 4 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant organization does not have the ability to pay interest, and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

ADDITIONAL TERMS FOR CRIMINAL MONETARY PENALTIES

The defendant must pay $1,000,000.00 to the Virginia Department of Health Professions in recognition of direct assistance provided by DHP to the United States during the investigation.

AO 245E (Rev. 12/03 - VAW Additions 3/04) Judgment in a Criminal Case for Organizational Defendants
Sheet 4 - Schedule of Payments

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

SCHEDULE OF PAYMENTS

Having assessed the organization's ability to pay, payment of the total criminal monetary penalties are due as follows:

A ☐ Lump sum payment of $ _____ due immediately, balance due

☐ not later than _____ , or
☐ in accordance with ☐ C or ☐ D below; or

B ☐ Payment to begin immediately (may be combined with ☐ C or ☐ D below); or

C ☐ Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

D ☒ Special instructions regarding the payment of criminal monetary penalties:

All amounts have been paid in full.

All criminal monetary penalties are made to the clerk of the court.

The defendant organization shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant organization shall pay the cost of prosecution.

☐ The defendant organization shall pay the following court cost(s):

☒ The defendant organization shall forfeit the defendant organization's interest in the following property to the United States:
See attached Agreed Order of Forfeiture.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS 14 DAY OF FEB., 2020.

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2020	7/20/2020	AL	Birmingham	Birmingham

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
20-L-0045	Alabama Board of Pharmacy

Reason/Charge
Violation of Alabama Pharmacy Practice Act

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health international, Inc.	N/A

Name of Business/Industry/Entity
Animal Health international, Inc.

Provide explanation below:

On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine in the amount of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Boaz, Alabama wholesale drug distributor license.

Original Signature (electronic, copies or stamps not accepted)

11/27/23
Date

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
ANIMAL HEALTH INTERNATIONAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesaler	)	**CASE NO: 20-L-0045**
Permit Number: 195552	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. (hereinafter referred to as "AHI ") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and AHI, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that AHI violated the applicable provisions based upon the conduct set out in Count One of the Statement.

2. AHI shall pay to the Board an administrative fine in the amount of Two Thousand Five Hundred dollars ($2,500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and AHI shall not attempt to discharge the same in any bankruptcy proceeding.

3. That AHI expressly waives its rights pursuant to the Alabama Pharmacy

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. AHI further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, AHI hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That AHI agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That AHI acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. AHI acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

DONE this the 17th day of July, 2020.

Animal Health International, Inc.

By: _____
Its: Secretary

Edward D. Rickert
_____
Edward D. Rickert, Attorney for Animal Health International, Inc.

DONE this the 20 day of JULY, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Ralph E. Sorrell
Ralph E. Sorrell, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Wholesaler Permit Number: 195552	)	**CASE NO: 20-L-0045**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Animal Health International, Inc.
1202 Esi Drive
Springdale, Arizona 72764

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 23, 2020 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Animal Health International, Inc. (AHI) as a Wholesaler should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that AHI has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

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(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your Plea Agreement dated February 13, 2020 in a case styled United States of America v Animal Health International, Inc. in the United States District Court for the Western District of Virginia, Criminal Case No. 1:20-cv-00007. A copy of the Plea Agreement

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

and Information referenced in the Plea Agreement are attached hereto collectively as Exhibit "A".

The Board alleges that each act of misbranding as described in Exhibit "A" is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 24th day of April, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2020	7/20/2020	AL	Birmingham	Birmingham

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
20-L-0046	Alabama Board of Pharmacy

Reason/Charge
Violations of the Code of Alabama (1975) §34-23-32, §34-23-32.1, 34-23-92(11) and (12), §41-22-12

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health international, Inc.	N/A

Name of Business/Industry/Entity
Animal Health international, Inc.

Provide explanation below:

On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas wholesale drugdistributor license.

Kelley Kaz

Original Signature (electronic, copies or stamps not accepted)

11/17/23

Date

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

IN THE MATTER OF: **ANIMAL HEALTH INTERNATIONAL, INC.** **Wholesaler** **Permit Number: 400357**	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY** **CASE NO: 20-L-0046**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. (hereinafter referred to as "AHI ") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and AHI, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that AHI violated the applicable provisions based upon the conduct set out in Count One of the Statement.

2. AHI shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and AHI shall not attempt to discharge the same in any bankruptcy proceeding.

3. That AHI expressly waives its rights pursuant to the Alabama Pharmacy

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. AHI further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, AHI hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That AHI agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That AHI acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. AHI acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

DONE this the 17th day of July, 2020.

Animal Health International, Inc.

By: _____
Its: Secretary

Edward D. Rickert

Edward D. Rickert, Attorney for Animal Health International, Inc.

DONE this the 20 day of JULY, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Ralph E. Sorrell
Ralph E. Sorrell, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Wholesaler Permit Number: 400357	)	**CASE NO: 20-L-0046**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Animal Health International, Inc.
990 River Oaks Road
Boaz, Alabama 35957

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 23, 2020 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Animal Health International, Inc. (AHI) as a Wholesaler should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that AHI has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your Plea Agreement dated February 13, 2020 in a case styled United States of America v Animal Health International, Inc. in the United States District Court for the Western District of Virginia, Criminal Case No. 1:20-cv-00007. A copy of the Plea Agreement

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

and Information referenced in the Plea Agreement are attached hereto collectively as Exhibit "A".

The Board alleges that each act of misbranding as described in Exhibit "A" is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 24th day of April, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/15/2022	12/15/2022	FL	Tallahassee	Leon
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2021-39162		Florida State Board of Pharmacy		
Reason/Charge				
Violations of Florida Statutes (2021) Section 20.43 and chapters 456 and 465				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Animal Health International, Inc.		N/A		
Name of Business/Industry/Entity				
Animal Health International, Inc.				

Provide explanation below:

On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license (#PH32369). This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

Final Order No. DOH-22-15565 -MQA

FILED DATE - DEC 28 2022
Department of Health
By: Amy L. Carraway
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH, PETITIONER, v. ANIMAL HEALTH INTERNATIONAL, INC. RESPONDENT.	CASE NO.: 2021-39162 LICENSE NO.: PH 32369

FINAL ORDER
APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to section 120.57(4), *Florida Statutes*, on December 15, 2022, at a duly-noticed public meeting held in Orlando, Florida, for consideration of a Settlement Agreement (hereinafter "Settlement Agreement" and attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby **ORDERED AND ADJUDGED:**

1. The Settlement Agreement as submitted is hereby approved, adopted, and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

2. The agreed amount of Costs in this case are $650.11 which shall be paid in the manner outlined in the incorporated Settlement Agreement.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

[SIGNATURE BLOCK ON FOLLOWING PAGE]

DONE AND ORDERED this 28th day of December, 2022.

BOARD OF PHARMACY

GE Mills for
Jessica L. Sapp, Executive Director
On Behalf of David Wright, BPharm, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to **Animal Health International, Inc.** at 2915 Rocky Mountain Avenue, Suite 400, Loveland, CO 80538 and 9146 West Wolcott Industrial Parkway, Wolcott, IN 47995; by electronic mail to **Kara H. Aikens**, Assistant Attorney General, Office of the Attorney General, at kara.aikens@myfloridalegal.com; and by electronic mail to **Alejandro Camacho**, Assistant General Counsel, Prosecution Services Unit, at alejandro.camacho@flhealth.gov, and **Edward Rickert**, Counsel to Respondent, at edward.richert@quarles.com this 28th day of December, 2022.

Anna L. Camacho
DEPUTY AGENCY CLERK

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2021-39162**

ANIMAL HEALTH INTERNATIONAL, INC.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy ("Board") as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **Animal Health International, Inc.**, was a permitted **non-resident pharmacy** in the state of Florida, having been issued permit number **PH29236**. Respondent's mailing address of record is 2915 Rocky Mountain Avenue, Ste. 400, Loveland, Colorado 80538.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health ("Department") and properly served upon Respondent, with violations of Chapters 456 and/or 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that they are subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Fine**- The Board of Pharmacy shall impose an administrative fine of **THREE THOUSAND FIVE HUNDRED DOLLARS ($3,500.00).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

2. **Costs**- The Board of Pharmacy shall impose the total administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FOUR HUNDRED DOLLARS ($1,400.00)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

3. **Correction of Alleged Deficiencies**- At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

4. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated

into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

6. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

7. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any

of its members from further participation, consideration, or resolution of these proceedings.

8. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

9. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

10. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

11. **Current Addresses**- Respondent shall keep current their mailing address and their practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

12. **Time of the Essence**- Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 6th day of December, 2022.

Institutional Representative for
Animal Health International, Inc.
CASE NO. 2021-39162

STATE OF Minnesota
COUNTY OF Wright

Sworn to (or affirmed) and subscribed before me by means of ☒ physical presence or ☐ online notarization, this 6th day of December, 2022, by Jeffrey Wigfield.

MICHELE CORINNE HALVERSON
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/26

Signature of Notary Public
Print, Type or Stamp Commissioned name of Notary Public
My Commission Expires: 01/31/2026

Personally Known_____ OR Produced Identification MN Drivers License

Type of Identification Produced MN Drivers License

APPROVED this 9th day of December, 2022.

Joseph A. Ladapo, MD, PhD
State Surgeon General

Alejandro Camacho
Assistant General Counsel

Counsel for Petitioner
Alejandro Camacho
Florida Bar No. 1018880
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 558-9839
Fax: (850) 245-4662

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2021-39162**

ANIMAL HEALTH INTERNATIONAL, INC.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Animal Health International, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to section 20.43, Florida Statutes (2021), and chapters 456 and 465, Florida Statutes (2021).

2. At all times material to this Administrative Complaint, Respondent was a permitted non-resident pharmacy within the state of Florida, having been issued license number PH29236.

3. Respondent's mailing address of record is 2915 Rocky Mountain Avenue, Suite 400, Loveland, Colorado 80538.

4. At all times material to this Administrative Complaint, Respondent was physically located at 9146 West Wolcott Industrial Parkway, Wolcott, Indiana 47995.

5. On or about February 14, 2020, in the United States District Court, Western District of Virginia, case 1:20-CR-00007, Respondent pled guilty to and/or was convicted of a misdemeanor count of Introduction of Misbranded Drugs into Interstate Commerce, a crime in violation of Title 21, United States Code, sections 331(a), 333(a)(1), and 352(f)(1).

6. The Introduction of Misbranded Drugs into Interstate Commerce count involved allegations that between on or about January 2012 and May 2015, Respondent was not properly licensed to ship veterinary prescription drugs from its Wolcott, Indiana, location to Virginia or Tennessee.

7. Section 465.016(1)(e), Florida Statutes (2021), provides that violating 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act, constitute grounds for disciplinary action.

8. Introduction of Misbranded Drugs into Interstate Commerce in violation of Title 21, United States Code, sections 331(a), 333(a)(1), and 352(f)(1), is a crime related to the practice of, and/or the ability to practice, pharmacy.

9. Section 456.072(1)(c), Florida Statutes (2021), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession constitutes grounds for disciplinary action.

10. As set forth above, Respondent was convicted of, and/or entered a plea of guilty to, a crime in the United States District Court, Western District of Virginia, which relates to the practice of, and/or the ability to practice, Respondent's profession.

11. Based on the foregoing, Respondent violated section 456.072(1)(c).

[*Remainder of Page Intentionally Left Blank.*]

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 23rd day of June 2022.

Joseph A. Ladapo, MD, PhD
State Surgeon General

By: */s/ Alejandro Camacho*
Alejandro Camacho
Assistant General Counsel
FL DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar Number 1018880
Phone: (850) 558-9839
Fax: (850) 245-4662
Alejandro.Camacho@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Elizabeth Eubanks*
DATE: June 23, 2022

PCP Meeting: June 23, 2022
PCP Members: Mikhael & Mesaros

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Animal Health International, Inc.

Physical Address: 203 Fourth Avenue West

City: Twin Falls State: ID Zip: 83301

Mailing Address (if different from physical address): 1031 Mendota Heights Road; Attn: Regulatory Licensing

City: Saint Paul State: MN Zip: 55120

Telephone: 970-347-3322 Website: www.animalhealthinternational.com

Name of Designated Representative (DR): Luke Theberge

Licensing Company Email: FacilityLicensing@Pattersoncompanies.com DR Email: Luke.Theberge@animalhealthinternational.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others: Veterinary Legend Drugs	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Boehringer Ingelheim
Address: PO Box 22748 City: New York State: NY Zip: 10087

Name: Merck Animal Health
Address: BOX 198428 City: Atlanta State: GA Zip: 30384

Name: Norbrook Inc.
Address: Station Works Camlough Road City: Newry State: GB Zip: BT35 6JP

Name: Zoetis US LLC
Address: PO Box 419022 City: Boston State: MA Zip: 02241

Section 4: Publicly Traded Corporation

State of Incorporation: Colorado
Parent Company (if any): Patterson Companies, Inc.
Corporation Name: Animal Health International, Inc.
Mailing Address: 1031 Mendota Heights Road, Attn: Regulatory Licensing
City: Saint Paul State: MN Zip: 55120
Telephone: 651-686-1957 Email: FacilityLicensing@Pattersoncompanies.com
Contact Person Name: Kelley Karau

Date of SEC Registration: 05/13/1996 | SEC Registration Number: 0-20572 | Stock Exchange Symbol: PDCO

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Animal Health International, Inc.

Facility Name

Kevin M Pohlman

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/16/23

Date

Board Use Only	Date Received: 11/29/23	Amount: $1000 - CC

ANIMAL HEALTH INTERNATIONAL, INC.

(LIST OF OFFICERS & DIRECTORS)

DIRECTORS

Donald J. Zurbay	1031 Mendota Heights Rd, St. Paul, MN 55120
Les B. Korsh	1031 Mendota Heights Rd, St. Paul, MN 55120

OFFICERS

Donald J. Zurbay	CEO	1031 Mendota Heights Rd, St. Paul, MN 55120
Kevin M. Pohlman	President	[redacted]
Kevin M. Barry	VP, CFO & Treasurer	1031 Mendota Heights Rd, St. Paul, MN 55120
Les B. Korsh	Corporate Secretary	1031 Mendota Heights Rd, St. Paul, MN 55120

Incorporated - Minnesota
Date - 3/22/96
Federal ID# - 41-1833619

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc. 1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515

Animal Health International, Inc. – Top Shareholders

Corporate Address:	2915 Rocky Mountain Ave. Suite 400 Loveland, CO 80538
Phone:	970-353-2000
FEIN:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Facility:	Animal Health International, Inc.	
Address:	203 Fourth Avenue West Twin Falls, ID 83301	
Shareholders:	BlackRock Fund Advisors	7.36%
	The Vanguard Group, Inc.	5.53%
	Dimensional Fund Advisors, L.P. (US)	10.96%
	State Street Global Advisors (SSgA)	5.64%

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Animal Health International, Inc.

is a

Corporation

formed or registered on 05/16/1967 under the law of Colorado, has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 19871193550 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 10/17/2023 that have been posted, and by documents delivered to this office electronically through 10/18/2023 @ 09:07:16 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 10/18/2023 @ 09:07:16 in accordance with applicable law. This certificate is assigned Confirmation Number 15410402 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

IDAHO STATE BOARD OF PHARMACY
P.O. Box 83720 Boise, Idaho 83720-0067
Telephone: (208) 334-2356 FAX: (208) 334-3536

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Idaho State Board of Pharmacy statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below.

ANIMAL HEALTH INTERNATIONAL

Wholesale Distributor License
License No: W41110

ISSUED: 02/02/2016 EXPIRES: 12/31/2024

The official status and business address of this license must be verified at Idaho Board of Pharmacy License Verification.
http://bop.idaho.gov

Physical Address:
203 4TH AVE W
Twin Falls, ID 833016313

597530
Printed: 11/6/2023

Nicki Chopski

NICKI CHOPSKI PHARMD
EXECUTIVE DIRECTOR

Animal Health INTERNATIONAL
2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Parent Company:	Patterson Companies, Inc. 1031 Mendota Heights Road Saint Paul, MN 55120
Ownership:	100%
FEIN:	41-0886515

Animal Health International, Inc. - Employees

Corporate Address:	2915 Rocky Mountain Ave. Suite 400 Loveland, CO 80538
Phone:	970-353-2000
FEIN:	84-0575063
State of Incorporation:	Colorado (5/16/1967)

Facility:	Animal Health International, Inc.
Address:	203 Fourth Avenue West Twin Falls, ID 83301

Employees:

Abram Guard
Brock Stroud
Cheyenne Stewart
Cory Adams
Dean Chandler
Douglas Alarcon
Greg Llamas
Kane Hutsell
Lance Morrison
Luke Theberge
Mary Vasquez
Michael Durfee
Nathan Streithorst
Paul Heinzman
Russell Mourton
Sean Whelan
Silvia Ortiz Vega
Stepheni Gray
Troy Westover

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended April 29, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File No. 0-20572

PATTERSON COMPANIES, INC.

(Exact name of registrant as specified in its charter)

Minnesota	**41-0886515**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1031 Mendota Heights Road
St. Paul, Minnesota 55120
(Address of principal executive offices including Zip Code)

Registrant's telephone number, including area code: (651) 686-1600

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $.01	PDCO	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐
Smaller reporting company	☐	Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (October 29, 2022) was approximately $2,521,000,000 (For purposes of this calculation all of the registrant's executive officers and directors are deemed affiliates.)

As of June 14, 2023, there were 95,294,000 shares of Common Stock of the registrant issued and outstanding.

Documents Incorporated By Reference

Portions of the registrant's definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year-end of April 29, 2023 are incorporated by reference into Part III.

FORM 10-K INDEX

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PART I

Item 1. BUSINESS

Forward-Looking Statements

The U.S. Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements to encourage companies to provide prospective information, so long as those statements are identified as forward-looking and are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those disclosed in the statement. Certain information of a non-historical nature contained in Items 1, 2, 3 and 7 of this Form 10-K includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding future financial performance, and the objectives and expectations of management. Forward-looking statements often include words such as "believes," "expects," "anticipates," "estimates," "intends," "plans," "seeks" or words of similar meaning, or future or conditional verbs, such as "will," "should," "could" or "may." Forward-looking statements are neither historical facts nor assurances of future performance. Instead, such statements, including, but not limited to, our statements regarding business strategy, growth strategy, competitive strengths, productivity and profitability enhancement, competition, new product and service introductions and liquidity and capital resources, are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions, as well as on assumptions made by and information currently available to management, and involve various risks and uncertainties, some of which are beyond our control.

Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not place undue reliance on any of these forward-looking statements. Any number of factors could affect our actual results and cause such results to differ materially from those contemplated by any forward-looking statements. Reference is made to "Risk Factors" in Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of this Form 10-K, for a discussion of certain factors that could cause actual operating results to differ materially from those expressed in any forward-looking statements. In light of these risks and uncertainties, there can be no assurance that the forward-looking information will in fact prove to be accurate. The order in which these factors appear should not be construed to indicate their relative importance or priority. We caution that these factors may not be exhaustive, accordingly, any forward-looking statements contained herein should not be relied upon as a prediction of actual results.

You should carefully consider these and other relevant factors and information which may be contained in this Form 10-K and in our other filings with the U.S. Securities and Exchange Commission, or SEC, when reviewing any forward-looking statement. Investors should understand it is impossible to predict or identify all such factors or risks. As such, you should not consider the risks identified in our SEC filings, to be a complete discussion of all potential risks or uncertainties.

Any forward-looking statement made in this Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We do not undertake any obligation to release publicly any revisions to any forward-looking statements whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

General

Patterson Companies, Inc. is a value-added specialty distributor serving the U.S. and Canadian dental supply markets and the U.S., Canadian and U.K. animal health supply markets. Patterson operates through its two strategic business units, Patterson Dental and Patterson Animal Health, offering similar products and services to different customer bases. Each business has a strong competitive position, serves a highly fragmented market that offers consolidation opportunities and offers relatively low-cost consumable supplies, which makes our value-added business proposition highly attractive to our customers. We believe that we have a strong brand identity as a value-added, full-service distributor with broad product and service offerings, having begun distributing dental supplies in 1877.

Business Overview

The following table sets forth consolidated net sales (in millions) by segment.

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Dental	$ 2,492	$ 2,516	$ 2,327
Animal Health	3,965	3,983	3,560
Corporate	14	—	25
Consolidated net sales	$ 6,471	$ 6,499	$ 5,912

Our strategically located fulfillment centers enable us to better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs. Our infrastructure also allows us to provide convenient ordering and rapid, accurate and complete order fulfillment.

Electronic commerce solutions have become an integral part of dental and animal health supply and distribution relationships. Our distribution business is characterized by rapid technological developments and intense competition. The continuing advancement of online commerce requires us to cost-effectively adapt to changing technologies, to enhance existing services and to develop and introduce a variety of new services to address the changing demands of consumers and our customers on a timely basis, particularly in response to competitive offerings. We believe that our tradition of reliable service, our name recognition and large customer base built on solid customer relationships, position us well to participate in this significant aspect of the distribution business. We continue to explore methods to improve and expand our Internet presence and capabilities, including our online commerce offerings and our use of various social media outlets.

Patterson became publicly traded in 1992 and is a corporation organized under the laws of the state of Minnesota. We are headquartered in St. Paul, Minnesota. Our principal executive offices are located at 1031 Mendota Heights Road, St. Paul, Minnesota 55120, and our telephone number is (651) 686-1600. Unless the context specifically requires otherwise, the terms the "Company," "Patterson," "we," "us" and "our" mean Patterson Companies, Inc., a Minnesota corporation, and its consolidated subsidiaries.

The Specialty Distribution Markets We Serve

We provide manufacturers with cost effective logistics and high-caliber sales professionals to access a geographically diverse customer base, which is critical to the supply chain for the markets we serve. We provide our customers with an array of value-added services, a dedicated and highly skilled sales team, and a broad selection of products through a single channel, thereby helping them efficiently manage their ordering process. Due in part to the inability of our customers to store and manage large quantities of supplies at their locations, the distribution of supplies and small equipment has been characterized by frequent, small-quantity orders, and a need for rapid, reliable and substantially-complete order fulfillment. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

We believe that consolidation within the industry will continue as distributors, particularly those with limited financial, operating and marketing resources, seek to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

Dental Supply Market

The dental supply market we serve consists of geographically dispersed and highly fragmented dental practices. Customers range in size from sole practitioners to large group practices, often called Dental Service Organizations ("DSO's"). According to the American Dental Association and the Canadian Dental Association, there are approximately 203,000 dentists practicing in the U.S. and 25,000 dentists practicing in Canada. We believe the average dental practitioner purchases supplies from more than one supplier.

We believe the North American dental supply market continues to experience growth due to an increasing population, an aging population, advances in dentistry, demand for general, preventive and specialty services, increasing demand for new technologies that allow dentists to increase productivity, demand for infection control products, and insurance coverage by dental plans.

We support dental professionals through the many stock keeping units ("SKUs") that we offer, as well as through important value-added services, including equipment and technology installation and service, practice management software, electronic claims processing, financial services, and continuing education, all designed to help make a dental practice more efficient.

Animal Health Supply Market

The animal health supply market is a mix of production animal supply, which primarily serves food producing animals, consisting of beef and dairy cattle, swine and poultry and other species such as sheep and goats, and companion animal supply, which serves pets, primarily dogs, cats and horses. Similar to the dental supply market, the animal health supply market is highly fragmented and diverse. Our production animal customers include large animal veterinarians, beef producers (cow/calf, stocker and feedlots), dairy producers, poultry producers, swine producers and retail customers. Our companion animal customers are primarily small animal and equine veterinary clinics, including independently owned, corporates and groups. According to the American Veterinary Medical Association, there are more than 70,000 veterinarians in private practice in the U.S. and Canada. Furthermore, there are approximately 20,000 veterinarians in the U.K. practicing in veterinary outlets; however, we believe there has been a shift in the U.K. market toward consolidation of veterinary practices. National Veterinary Services Limited, is the market leader in the U.K. veterinary market, with the highest percentage of buying groups and corporations as customers compared to its competitors, and the highest share position in that country overall.

The global animal health supply market continues to experience growth, and we believe that trend will continue for the foreseeable future. We support our animal health customers through the distribution of biologicals, pharmaceuticals, parasiticides, supplies, including our own private label brands, and equipment. We also supply a full portfolio of technologies, software, services and solutions to all segments and channels of our broad customer base. We actively engage in the development, sale and distribution of inventory, accounting and health management systems to enhance customer operating efficiencies and assist our customers in managing risk. Within the companion animal supply market, we anticipate increasing demand for veterinary services due to the following factors: the increasing number of households with companion animals, increased pet adoption rates and increased expenditures on animal health and preventative care, an aging pet population, advancements in animal health products and diagnostic testing, and extensive marketing programs sponsored by companion animal nutrition and pharmaceutical companies.

We anticipate the macroeconomic trend of global population growth and corresponding demand for protein will be favorable to the production animal segment in the future. Likewise, the rise in disposable income, especially in developing countries will be a key driver of future growth. However; product sales in the production animal supply market are more likely to be impacted by volatility in the market such as commodity prices, changes in weather patterns, and trends in the general economy. Many factors can influence how long cattle will graze and consequently the number of days an animal is on feed during a finishing phase. Supply and demand dynamics and economic trends can shift the number of animals treated, the timing of when animals are treated, to what extent they are treated and with which products they are treated. Historically, sales in this market have been largely driven by spending on animal health products to improve productivity, weight gain and disease prevention, as well as a growing focus on health and wellness of the animals, safety, and efficiency in livestock production.

Competition

The distribution industry is highly competitive. It consists principally of national, regional and local full-service distributors. Substantially all of the products we sell are available to customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Some manufacturers also sell directly to end-users, thereby eliminating or reducing our role and that of other distributors.

We compete with other distributors, as well as several manufacturers, of dental and animal health products, on the basis of price, breadth of product line, customer service and value-added products and services. To differentiate ourselves from our competition we deploy a strategy of premium customer service with multiple value-added components, a highly qualified and motivated sales force, highly-trained and experienced service technicians, an extensive breadth and mix of products and services, technology solutions allowing customers to easily access our inventory, accurate and timely delivery of product, strategic location of sales offices and fulfillment centers, and competitive pricing.

In the U.S. and Canadian dental supply market, we compete against Henry Schein, Inc., Benco Dental Supply Company, Burkhart Dental Supply and hundreds of distributors that operate on a regional or local level, or online. Also, as noted above, some manufacturers sell directly to end users. With regard to our dental practice

management software, we compete against numerous offerings, including those from Henry Schein, Inc. and Carestream Dental.

In the U.S. and Canadian animal health supply market, our primary competitors are AmerisourceBergen/MWI Animal Health and Covetrus, Inc. We also compete against a number of regional and local animal health distributors, some manufacturers that sell direct to end users and several alternative channel market providers that sell through digital platforms to production animal operators, animal health product retailers and veterinarians. Additionally, major U.S. online e-commerce retailers such as Amazon and Chewy.com have become licensed as veterinary mail order pharmacies, which enables them to offer pharmacy products directly to consumers in all 50 U.S. states. In the animal health practice management market, our primary competitors are IDEXX Laboratories, Inc. and Covetrus, Inc. We face significant competition in the animal health supply market in the U.K., where we compete on the basis of price and customer service with several large competitors, including Covetrus, Inc. and AmerisourceBergen. We also compete directly with pharmaceutical companies who sell certain products or services directly to the customer.

Successful distributors are increasingly providing value-added services in addition to the products they have traditionally provided. We believe that to remain competitive we must continue to add value to the distribution channel, while removing unnecessary costs associated with product movement. Significant price reductions by our competitors could result in competitive harm. Any of these competitive pressures may materially adversely affect our operating results.

Competitive Strengths

We have more than 140 years of experience in distributing products resulting in strong awareness of the Patterson brand. Although further information regarding these competitive strengths is set forth below in the discussion of our two strategic business units, our competitive strengths include:

- *Broad product and service offerings at competitive prices.* We sell approximately 200,000 SKUs to our customers, including many proprietary branded products. We believe that our proprietary branded products and our competitive pricing strategy have generated a loyal customer base that is confident in our brands. Our product offerings include consumables, equipment, software and various technologies. Our value-added services include practice management software, office design, equipment installation and maintenance, and financing.

- *Focus on customer relationships and exceptional customer service.* Our sales and marketing efforts are designed to establish and solidify customer relationships through personal visits by field sales representatives, interaction via phone with sales representatives, web-based activities including e-commerce and frequent direct marketing, emphasizing our broad product lines, competitive prices and ease of order placement. We focus on providing our customers with exceptional order fulfillment and a streamlined ordering process.

- *Cost-effective purchasing and efficient distribution.* We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitive-pricing provider of dental and animal health products. We strive to maintain optimal inventory levels to satisfy customer demand for prompt and complete order fulfillment through our distribution of products from strategically located fulfillment centers.

Business Strategy

Our objective is to continue to expand as a leading value-added distributor of dental and animal health products and services. To accomplish this, we will apply our competitive strengths in executing the following strategies:

- *Emphasizing our differentiated, value-added, full-service capabilities.* We are positioned to meet virtually all of the needs of dental practitioners, veterinarians, production animal operators and animal health product retailers by providing a broad range of consumable supplies, technology, equipment, software and value-added services. We believe our knowledgeable sales representatives can create customer intimacy and loyalty by providing an informational, consultative approach to our customers, linking them to the industries we serve. Our value-added strategy is further supported by our equipment specialists who offer consultation on design, equipment requirements and financing, our service technicians who perform equipment installation, maintenance and repair services, our business development professionals who provide business tools and educational programs to our customers, and our technology advisors who provide guidance on integrating technology solutions.

- *Using technology to enhance customer service.* As part of our commitment to providing superior customer service, we offer our customers easy order placement. Although we offer computerized order entry systems that we believe help establish relationships with new customers and increase loyalty among existing customers, predominant platforms for ordering today include www.pattersondental.com, www.pattersonvet.com and www.animalhealthinternational.com. The use of these methods of ordering enables our sales representatives to spend more time with existing and prospective customers. Our Internet environment includes order entry, customer support for digital and our proprietary products, customer-loyalty program reports and services, and access to articles and manufacturers' product information. We also provide real-time customer and sales information to our sales force, managers and vendors via the Internet. In addition, the Patterson Technology Center ("PTC") differentiates Patterson from our competition by providing deep and thorough expertise in practice management software and other advanced equipment and technology clinical solutions. In addition to trouble-shooting through the PTC's support center, customers can access various service capabilities offered by the PTC, including electronic claims and statement processing and system back-up capabilities.

- *Continuing to improve operating efficiencies.* We continue to implement programs designed to improve our operating efficiencies and allow for continued sales growth. This strategy includes our continuing investment in management information systems and consolidation and leveraging of fulfillment centers and sales branches between our operating segments. In addition, we have established shared sales branch offices in several locations.

- *Growing through internal expansion and acquisitions.* We intend to continue to grow by hiring sales representatives, hiring and training sales professionals, opening additional locations as needed, and acquiring other companies in order to enter new, or more deeply penetrate existing, markets, gain access to additional product lines, and expand our customer base. We believe both of our operating segments are well positioned to take advantage of expected continued consolidation in our markets.

Dental Segment - Products, Services and Sources of Supply

Patterson Dental, one of the two largest distributors of dental products in North America, has operations in the U.S. and Canada. As a full-service, value-added supplier to over 100,000 dental practices, dental laboratories, educational institutions, and community health centers, Patterson Dental provides consumable products (including infection control, restorative materials, and instruments); basic and advanced technology and dental equipment; and innovative practice optimization solutions, including practice management software, e-commerce, revenue cycle management, patient engagement solutions, and clinical and patient education. Patterson Dental sells approximately 100,000 SKUs, of which approximately 3,500 are private-label products sold under the Patterson brand. Patterson Dental also offers customers a range of related services including software and design services, maintenance and repair, and equipment financing. Net sales and operating income were $2.5 billion and $237 million in fiscal 2023, respectively.

The following table sets forth the percentage of total sales by the principal categories of products and services offered to our dental segment customers:

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Consumable	55 %	57 %	56 %
Equipment	33	32	31
Value-added services and other	12	11	13
	100 %	100 %	100 %

Patterson Dental obtains products from hundreds of vendors, most of which are non-exclusive. While there is generally more than one source of supply for most of the categories of products we sell, the concentration of business with key suppliers is considerable, as consolidation has increased among manufacturers. In fiscal 2023, 2022 and 2021, Patterson Dental's top ten supply vendors accounted for approximately 58%, 56% and 57% of the total cost of sales, respectively. The top vendor accounted for 24%, 24% and 25% of the total cost of sales in fiscal 2023, 2022 and 2021, respectively.

Animal Health Segment - Products, Services and Sources of Supply

Patterson Animal Health is a leading distributor of animal health products in the U.S., Canada and the U.K. We sell approximately 100,000 SKUs, of which approximately 2,000 are private-label. Products are sourced from over 2,000 manufacturers to over 50,000 customers in the highly fragmented animal health supply market. Products we distribute include pharmaceuticals, vaccines, parasiticides, diagnostics, prescription and non-prescription diets, nutritionals, consumable supplies and equipment. We offer a private label portfolio of products to veterinarians, producers, and retailers through our Aspen, First Companion and Patterson Veterinary brands. We also provide a range of value-added services to our customers. Within our companion animal supply market, our principal customers are companion-pet and equine veterinarians, veterinary clinics, public and private institutions, and shelters. In our production animal supply market, our principal customers are large animal veterinarians, production animal operators and animal health product retailers. Consumer demand for alternative means of sourcing product through digital platforms is an evolving dynamic in our industry. We provide digital home delivery solutions to allow us to evolve with the market. Net sales and operating income were $4.0 billion and $127 million in fiscal 2023, respectively.

The following table sets forth the percentage of total sales by the principal categories of products and services offered to our animal health segment customers:

	Fiscal Year Ended		
	April 29, 2023	April 30, 2022	April 24, 2021
Consumable	96 %	96 %	96 %
Equipment	3	3	3
Value-added services and other	1	1	1
	100 %	100 %	100 %

Patterson Animal Health obtains products from over 2,000 vendors globally. While Patterson Animal Health makes purchases from many vendors and there is generally more than one source of supply for most of the categories of products, the concentration of business with key vendors is considerable, as consolidation has increased among manufacturers. In fiscal 2023, 2022 and 2021, Patterson Animal Health's top 10 manufacturers comprised approximately 66%, 66% and 70% of the total cost of sales, respectively, and the single largest supplier comprised approximately 24%, 23% and 20% in of the total cost of sales 2023, 2022 and 2021, respectively.

Sales, Marketing and Distribution

During fiscal 2023, we sold products or services to over 100,000 customers who made one or more purchases during the year. Our customers include dentists, laboratories, institutions, other healthcare professionals, veterinarians, other animal health professionals, production animal operators and animal health product retailers. No single customer accounted for more than 10% of sales during fiscal 2023, and we are not dependent on any single customer or geographic group of customers.

We have offices throughout the U.S. and Canada so that we can provide a presence in the market and decision-making near the customer. Patterson Animal Health also has a central office in the U.K. Our offices, or sales branches, are staffed with a complete complement of our capabilities, including sales, customer service and technical service personnel, as well as a local manager who has decision-making authority with regard to customer-related transactions and issues.

A primary component of our value-added approach is our professional sales and support organization. Due to the highly-fragmented nature of the markets we serve, we believe that our unique combination of field-based and call-center sales and support teams is critical to reaching potential customers and providing a differentiated customer experience. Our sales representatives play an indispensable and critical role in managing a practice's supply chain and in introducing new products and technologies.

In the U.S. and Canada, customer service representatives in call centers work in tandem with our sales representatives, providing a dual coverage approach for individual customers. In addition to processing orders, customer service representatives are responsible for assisting customers with ordering, informing customers of monthly promotions, and responding to general inquiries. In the U.K., our customer service team is primarily responsible for handling customer inquiries and resolving issues.

To assist our customers with their purchasing decisions, we provide a multi-touchpoint shopping experience. From print to digital, this seamless experience is inclusive of products and services information. Patterson offers online and in-print showcases of our expansive merchandise and equipment offerings, including digital imaging and computer-aided design and computer-aided manufacturing ("CAD/CAM") technologies, hand-held and similar instruments, sundries, office design, e-services, repair and support assistance, as well as financial services. We also promote select products and services through publications, including *On Target* and *Advantage* in the U.S. and *Patterson Post* in Canada in our Dental segment, and *Insight* in the U.S. and *The Cube* in the U.K. in our Animal Health segment. Additional direct marketing tools that we utilize include customer loyalty programs, social media, and participation in trade shows.

We believe that responsive delivery of quality supplies and equipment is key to customer satisfaction. We ship consumable supplies from our strategically located fulfillment centers in the U.S. and Canada. In the U.K., orders are accepted in a centralized fulfillment center and shipped nationwide to one of our depots located throughout the country at which pre-packed orders are sorted by route for delivery to customers. Orders for consumable supplies can be placed through our sales representatives, customer service representatives or electronically 24 hours a day, seven days a week. Rapid and accurate order fulfillment is another principal component of our value-added approach.

In order to assure the availability of our broad product lines for prompt delivery to customers, we must maintain sufficient inventories at our fulfillment centers. Purchasing of consumables and standard equipment is centralized, and our purchasing department uses a real-time perpetual inventory system to manage inventory levels. Our inventory consists mostly of consumable supply items and pharmaceutical products.

Impacts of COVID-19

The COVID-19 pandemic had a significant impact on our businesses in fiscal 2021 as we implemented cost reduction measures in response to closures and other steps taken by governmental authorities. In response, management adapted our business practices with respect to employee travel, employee work locations, and cancellation of physical participation in meetings, events and conferences. Management also took proactive steps with respect to our liquidity position. Within our Dental segment, supply chain disruptions and an increased demand for PPE initially resulted in back orders of PPE, causing substantial price increases. We had to prepay suppliers in order to obtain PPE for resale to our customers, and as manufacturing caught up to increased demand for PPE, prices dropped, impacting our margins and requiring us to write down certain inventory.

In our markets of the U.S., Canada, and the UK, restrictive measures have now been lifted and the World Health Organization declared an end to the COVID-19 pandemic. Concerns remain that our markets could see a resurgence of COVID-19 cases or the emergence of new wide-spread public health outbreaks, triggering additional impacts on our businesses. There is continued uncertainty around the duration and ultimate impact of COVID-19 and other global health concerns.

Refer to Part I, Item 1A, "Risk Factors," and Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," within this Annual Report for further information on the impacts to our business and results of operations, our dividends, liquidity and debt arrangements, and associated risks and uncertainties.

Geographic Information

For information on revenues and long-lived assets of our segments by geographic area, see Note 14 to the Consolidated Financial Statements.

Seasonality and Other Factors Affecting Our Business and Quarterly Results

Our business in general is not seasonal; however, there are some products that typically sell more often during the winter or summer season. In any given month, unusual weather patterns (e.g., unusually hot or cold weather) could impact the sales volumes of these products, either positively or negatively. In addition, we experience fluctuations in quarterly earnings. As a result, we may fail to meet or exceed the expectations of securities analysts and investors, which could cause our stock price to decline. Quarterly results may be materially adversely affected by a variety of factors, including:

- timing and amount of sales and marketing expenditures;
- timing of pricing changes offered by our suppliers;

- timing of the introduction of new products and services by our suppliers;
- changes in or availability of supplier contracts or rebate programs;
- supplier rebates based upon attaining certain growth goals;
- changes in the way suppliers introduce or deliver products to market;
- costs of developing new applications and services;
- our ability to correctly identify customer needs and preferences and predict future needs and preferences;
- uncertainties regarding potential significant breaches of data security or disruptions of our information technology systems;
- regulatory actions, or government regulation generally;
- loss of sales representatives;
- costs related to acquisitions and/or integrations of technologies or businesses;
- costs associated with our self-insured insurance programs;
- general market and economic conditions, as discussed in Item 1A: Risk Factors, including pandemic, macro-economic conditions, increased fuel and energy costs, consumer confidence, as well as conditions specific to the supply and distribution industry and related industries;
- our success in establishing or maintaining business relationships;
- difficulties of manufacturers in developing and manufacturing products;
- product demand and availability, or product recalls by manufacturers;
- exposure to product liability and other claims in the event that the use of the products we sell results in injury;
- increases in shipping costs or service issues with our third-party shippers;
- fluctuations in the value of foreign currencies;
- goodwill impairment;
- changes in interest rates;
- restructuring costs;
- the adoption or repeal of legislation;
- changes in accounting principles; and
- litigation or regulatory judgments, fines, forfeitures, penalties, equitable remedies, expenses or settlements.

Governmental Regulation

We strive to be compliant with the applicable laws, regulations and guidance described below, and believe we have effective compliance programs and other controls in place to ensure substantial compliance. However, compliance is not guaranteed either now or in the future, as certain laws, regulations and guidance may be subject to varying and evolving interpretations that could affect our ability to comply, as well as future changes, additions and enforcement approaches, including political changes. Additionally, our policies and procedures may not always protect us from reckless or criminal acts committed by our employees or our agents. When we discover situations of non-compliance we seek to remedy them and bring the affected area back into compliance.

President Biden's administration (the "Biden Administration") has indicated that it will be more aggressive in its pursuit of alleged violations of law, and has revoked certain guidance that would have limited governmental use of informal agency guidance to pursue potential violations, and has stated that it is more prepared to pursue individuals for corporate law violations, including an aggressive approach to anti-corruption activities. Changes to applicable laws, regulations and guidance described below, as well as related administrative or judicial interpretations, may require us to update or revise our operations, services, marketing practices, and compliance programs and controls, and may impose additional and unforeseen costs on us, pose new or previously immaterial risks to us, or may otherwise have a material adverse effect on our business, results of operations and financial condition.

Federal, state and certain foreign governments have also increased enforcement activity in the health care sector, particularly in areas of fraud and abuse, anti-bribery and corruption, controlled substances handling, medical device regulations and data privacy and security standards. Our businesses are generally subject to numerous laws and regulations that could impact our financial performance. Failure to comply with such laws or regulations could be punishable by criminal or civil sanctions, which could materially adversely affect our business.

Operating, Security and Licensure Standards

Our dental and animal health supply businesses involve the distribution, importation, exportation, marketing and sale of, and third party payment for, pharmaceuticals and medical devices, and in this regard, we are subject to extensive local, state, federal and foreign governmental laws and regulations applicable to the distribution of pharmaceuticals and medical devices.

U.S. Federal Agencies

Certain of our businesses are required to register for permits and/or licenses with, and comply with operating and security standards of, the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Agriculture ("USDA"), the Environmental Protection Agency ("EPA"), the Food Safety Inspection Service ("FSIS"), the U.S. Drug Enforcement Administration ("DEA"), the Federal Trade Commission ("FTC"), and various state boards of pharmacy, state health departments and/or comparable state agencies as well as comparable foreign agencies, and certain accrediting bodies depending on the type of operations and location of product distribution, manufacturing or sale. These businesses include those that distribute, manufacture and/or repackage prescription pharmaceuticals and/or medical devices and/or HCT/P products, own pharmacy operations, or install, maintain or repair equipment.

FDA – the regulatory body that is responsible for the regulation of animal-health pharmaceuticals in the U.S. is the Center for Veterinary Medicine ("CVM") housed within the FDA.

- Generally, all animal-health pharmaceuticals are subject to pre-market review and must be shown to be safe, effective, and produced by a consistent method of manufacture as defined under the Federal Food, Drug and Cosmetic Act, as amended (the "FDC Act").
- If the drug is for food-producing animals, potential consequences for humans are also considered.
- Animal supplements generally are not required to obtain pre-market approval from the CVM, although they may be treated as food. Any substance that is added to, or is expected to become a component of, animal food must be used in accordance with food-additive regulations, unless it is generally recognized as safe, under the conditions of its intended use. Alternatively, the FDA may consider animal supplements to be drugs. The FDA has agreed to exercise enforcement discretion for such supplements if each such supplement meets certain conditions.
- Additionally, dental and medical devices we sell in the U.S. are generally classified by the FDA into a category that renders them subject to the same controls that apply to all medical devices, including regulations regarding alternation, misbranding, notification, record-keeping and good manufacturing practices.

USDA – the regulatory body in the U.S. for veterinary biologics, such as vaccines.

- The USDA's Center for Veterinary Biologics is responsible for the regulation of animal-health vaccines, including immunotherapeutics. Marketing of imported veterinary biological products in the U.S. requires a U.S. Veterinary Biological Product Permit. Veterinary biologics are subject to pre-market review and must be shown to be pure, safe, potent, and efficacious, as defined under the Virus Serum Toxin Act. The USDA requires post-licensing monitoring of these products.

EPA – the main regulatory body in the U.S. for veterinary pesticides is the EPA.

- The EPA's Office of Pesticide Programs is responsible for the regulation of pesticide products applied to animals.
- Animal-health pesticides are subject to pre-market review and must not cause "unreasonable adverse effects to man or the environment" as stated in the Federal Insecticide, Fungicide, and Rodenticide Act.
- Within the U.S., pesticide products that are approved by the EPA must also be approved by individual state pesticide authorities before distribution in that state. Post-approval monitoring of products is required, with reports provided to the EPA and some state regulatory agencies.

FSIS - the public health agency within the USDA.

- The FDA is authorized to determine the safety of substances (including "generally recognized as safe" substances, food additives and color additives), as well as prescribe their safe conditions of use. However,

although the FDA has the responsibility for determining the safety of substances, the FSIS still retains, under the tenets of the Federal Meat Inspection Act and the Poultry Products Inspection Act and their implementing regulations, the authority to determine whether new substances and new uses of previously approved substances are suitable for use in meat and poultry products.

DEA – under the Controlled Substances Act, distributors of controlled substances are required to obtain, and renew annually, registrations for their facilities from the DEA.

- Distributors are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling, and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times.
- Distributors are subject to inspection by the DEA.

FTC – the FTC regulates advertising pursuant to its authority to prevent "unfair or deceptive acts or practices in or affecting commerce" under the Federal Trade Commission Act.

- Advertising and promotion of animal-health products that are not subject to approval by the CVM may be challenged by the FTC, as well as by state attorneys general and by consumers under state consumer protection laws.
- The FTC will find an advertisement to be deceptive if it contains a representation or omission of fact that is likely to mislead consumers acting reasonably under the circumstances, the representation or omission is material, and if the advertiser does not possess and rely upon a reasonable basis, such as competent and reliable evidence, substantiating the claim.
- The FTC may address unfair or deceptive advertising practices through either an administrative adjudication or judicial enforcement action, including preliminary or permanent injunction.
- The FTC may also seek consumer redress from the advertiser in instances of dishonest or fraudulent conduct.

State Registrations – states may require registration of animal-drug distributors and wholesalers.

- Additional requirements may apply when the product is also a controlled substance. States work closely with the Association of American Feed Control Officials ("AAFCO") in their regulation of animal food.
- AAFCO's annual official publication contains model animal and pet-food labeling regulations that states may adopt.
- This publication is treated deferentially by the federal and state government agencies that regulate animal food. Many states require registration or licensing of animal-food distributors.
- States may also review and approve animal-food labels prior to sale of the product in their state.

We are also subject to foreign trade controls administered by certain U.S. government agencies, including the Bureau of Industry and Security within the Commerce Department, Customs and Border Protection within the Department of homeland Security and the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC).

The DEA, the FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our fulfillment centers, seize or order the recall of products and impose significant criminal, civil and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. Furthermore, compliance with legal requirements has required and may in the future require us to delay product release, sale or distribution, or institute voluntary recalls of, or other corrective action with respect to, products we sell, each of which could result in regulatory and enforcement actions, financial losses and potential reputational harm. Our customers are also subject to significant federal, state, local and foreign governmental regulation, which may affect our interactions with customers, including the design and functionality of the products we distribute.

Agencies Outside the U.S.

Since the U.K. formally left the EU on January 31, 2020, the Veterinary Medicines Directorate ("VMD") became the main regulatory body in the U.K. responsible for regulating and controlling veterinary pharmaceuticals. The U.K. and the EU reached a trade deal in December 2020, which went into effect in May 2021. The agreement includes regulatory and customs cooperation mechanisms, as well as provisions supporting open and fair competition. The Northern Ireland protocol, which is part of the trade deal, requires that VMD follow EU rules in Northern Ireland. Laws applying to the rest of the U.K. could now diverge but currently remain largely aligned.

U.S. Laws

Among the U.S. federal laws applicable to us are the Controlled Substances Act, the FDC Act, Section 361 of the Public Health Service Act, as well as laws regulating the billing of and reimbursement from government programs, such as Medicare and Medicaid, and from commercial payers. We are also subject to comparable foreign regulations.

The FDC Act, the Controlled Substances Act, their implementing regulations, and similar foreign laws generally regulate the introduction, manufacture, advertising, marketing and promotion, sampling, pricing and reimbursement, labeling, packaging, storage, handling, returning or recalling, reporting, and distribution of, and record keeping for, pharmaceuticals and medical devices shipped in interstate commerce, and states may similarly regulate such activities within the state. Furthermore, Section 361 of the Public Health Service Act, which provides authority to prevent the introduction, transmission, or spread of communicable diseases, serves as the legal basis for the FDA's regulation of human cells, tissues and cellular and tissue-based products, also known as "HCT/P products."

The federal Drug Quality and Security Act of 2013 brought about significant changes with respect to pharmaceutical supply chain requirements. Title II of this measure, known as the Drug Supply Chain Security Act ("DSCSA"), was first implemented in November 2014 and is being phased in over a period of 10 years. DSCSA is intended to build a national electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed in the U.S. The law's track and trace requirements applicable to manufacturers, wholesalers, third-party logistics providers (e.g., trading partners), repackagers and dispensers (e.g., pharmacies) of prescription drugs took effect in January 2015, and continues to be implemented. The DSCSA product tracing requirements replace the former FDA drug pedigree requirements and pre-empt certain state requirements that are inconsistent with, more stringent than, or in addition to, the DSCSA requirements.

The DSCSA also establishes certain requirements for the licensing and operation of prescription drug wholesalers and third party logistics providers ("3PLs"), and includes the eventual creation of national wholesaler and 3PL licenses in cases where states do not license such entities. The DSCSA requires that wholesalers and 3PLs distribute drugs in accordance with certain standards regarding the recordkeeping, storage and handling of prescription drugs. The DSCSA requires wholesalers and 3PLs to submit annual reports to the FDA, which include information regarding each state where the wholesaler or 3PL is licensed, the name and address of each facility and contact information. According to FDA guidance, states are pre-empted from imposing any licensing requirements that are inconsistent with, less stringent than, directly related to, or covered by the standards established by federal law in this area. Current state licensing requirements concerning wholesalers will remain in effect until the FDA issues new regulations as directed by the DSCSA.

The Food and Drug Administration Amendments Act of 2007 and the Food and Drug Administration Safety and Innovation Act of 2012 amended the FDC Act to require the FDA to promulgate regulations to implement a unique device identification ("UDI") system. The UDI rule phased in the implementation of the UDI regulations, generally beginning with the highest-risk devices (i.e., Class III medical devices) and ending with the lowest-risk devices. Most compliance dates were reached as of September 24, 2018, with a final set of requirements for low-risk devices being reached on September 24, 2022, which completed the phase in. However, in May 2021, the FDA issued an enforcement policy stating that it does not intend to object to the use of legacy identification numbers on device labels and packages for finished devices manufactured and labeled prior to September 24, 2023. The UDI regulations require "labelers" to include unique device identifiers ("UDIs"), with a content and format prescribed by the FDA and issued under a system operated by an FDA-accredited issuing agency, on the labels and packages of medical devices (including, but not limited to, certain software that qualifies as a medical device under FDA rules), and to directly mark certain devices with UDIs. The UDI regulations also require labelers to submit certain information concerning UDI-labeled devices to the FDA, much of which information is publicly available on an FDA database, the Global Unique Device Identification Database. On July 22, 2022, the FDA posted the final guidance regarding the Global Unique Device Identification Database called Unique Device Identification Policy Regarding

Compliance Dates for Class I and Unclassified Devices, Direct Marketing, and Global Unique Device Identification Database Requirements for Certain Devices. The UDI regulations and subsequent FDA guidance regarding the UDI requirements provide for certain exceptions, alternatives and time extensions. For example, the UDI regulations include a general exception for Class I devices exempt from the Quality System Regulation (other than record-keeping and complaint files). Regulated labelers include entities such as device manufacturers, repackagers, reprocessors and relabelers that cause a device's label to be applied or modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, and include certain of our businesses.

Under the Controlled Substances Act, as a distributor of controlled substances, we are required to obtain and renew annually registrations for our facilities from the DEA permitting us to handle controlled substances. We are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times. Non-controlled substances can also become subject to these controls. For example, law enforcement agencies are pressing for xylazine, which is an FDA-approved prescription veterinary tranquilizer found in certain analgesic products we distribute, to be listed as a federal controlled substance and several states, including Ohio, Pennsylvania, West Virginia and Florida, have already done so, which measures are likely to increase our cost of distributing such products. There have also been increasing efforts by various levels of government globally to regulate the pharmaceutical distribution system in order to prevent the introduction of counterfeit, adulterated or misbranded pharmaceuticals into the distribution system.

In addition, Section 301 of the National Organ Transplant Act, and a number of comparable state laws, impose civil and/or criminal penalties for the transfer of certain human tissue (for example, human bone products) for valuable consideration, while generally permitting payments for the reasonable costs incurred in procuring, processing, storing and distributing that tissue. We are also subject to foreign government regulation of such products.

Certain of our businesses are subject to various additional federal, state, local and foreign laws and regulations, including with respect to the sale, transportation, storage, handling and disposal of hazardous or potentially hazardous substances, and safe working conditions. In addition, certain of our businesses must operate in compliance with a variety of burdensome and complex billing and record keeping requirements in order to substantiate claims for payment under federal, state and commercial healthcare reimbursement programs.

Certain of our businesses also maintain contracts with governmental agencies and are subject to certain regulatory requirements specific to government contractors.

As disclosed in our prior periodic reports, our subsidiary Animal Health International was the subject of an investigation by the U.S. Attorney's Office for the Western District of Virginia, which resulted in Animal Health International pleading guilty to a strict-liability misdemeanor offense in connection with its failure to comply with federal law relating to the sales of prescription animal health products, and a total criminal fine and forfeiture of $52.8 million. In addition, Animal Health International and Patterson entered into a non-prosecution agreement for other non-compliant licensing, dispensing, distribution and related sales processes disclosed during the investigation and committed to undertake additional compliance program enhancements and provide compliance certifications through our reporting for fiscal 2023. This matter may continue to divert management's attention and cause us to suffer reputational harm. We also may be subject to other fines or penalties, equitable remedies (including but not limited to the suspension, revocation or non-renewal of licenses) and litigation. The occurrence of any of these events could adversely affect our business, results of operations and financial condition.

Other Regulations

Veterinary compounding pharmacies must comply with state and federal laws that govern the relationship between pharmacies and referral sources. The U.S. Federal Anti-Kickback Statute ("AKS") imposes criminal penalties against individuals and entities that pay or receive remuneration in return for referring an individual for service paid under a federal health care program. Veterinary compounding pharmacies have historically avoided scrutiny under the AKS because no federal programs are involved in veterinary compounding funding. However, most states have enacted statutes and regulations that mirror the AKS and, in some cases, are even broader than the AKS.

Various states have enacted business and insurance regulations prohibiting referral arrangements that result in the offer or acceptance of any rebate, refund, commission, discount or other consideration as compensation or inducement for referring patients, clients or customers. These regulations often encompass all health-care related professions, including pharmacies and veterinary practices.

Additionally, the promotion of regulated animal health products is controlled by regulations in many countries. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and endorsed by the applicable agency.

Antitrust and Consumer Protection

The U.S. federal government, most U.S. states and many foreign countries have antitrust laws that prohibit certain types of conduct deemed to be anti-competitive, as well as consumer protection laws that seek to protect consumers from improper business practices. At the U.S. federal level, the Federal Trade Commission oversees enforcement of these types of laws, and states have similar government agencies. Violations of antitrust or consumer protection laws may result in various sanctions, including criminal and civil penalties. Private plaintiffs also may bring, and have brought, civil lawsuits against us in the U.S. for alleged antitrust violations, including claims for treble damages. The Biden Administration has indicated increased antitrust enforcement and has been more aggressive in enforcement actions, including investigations and challenging restrictive contractual terms that it believes harm workers and competition.

Health Care Fraud

Certain of our businesses are subject to federal and state (and similar foreign) health care fraud and abuse, referral and reimbursement laws and regulations with respect to their operations. These laws and regulations govern different interactions, including but not limited to, those:

- prohibiting improper influence of or payments to healthcare professionals and government officials;
- setting out rules for when and how to engage healthcare professionals as vendors;
- requiring price reporting;
- requiring marketing of products within regulatory approval (i.e., on label);
- regulating the import and export of products;
- affecting the operation of our facilities and our distribution of products; and
- requiring disclosure of payments to healthcare professionals and entities.

Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by federal, state and other health care payers and programs. Several states apply their false claims and anti-kickback laws to all payers, including goods and services paid for directly by consumers. Certain additional state and federal laws, such as the federal Physician Self-Referral Law, commonly known as the "Stark Law," prohibit physicians and other health professionals from referring a patient to an entity with which the physician (or family member) has a financial relationship, for the furnishing of certain designated health services (for example, durable medical equipment and medical supplies), unless an exception applies. Violations of anti-kickback laws or the Stark Law may be enforced as violations of the federal False Claims Act.

The fraud and abuse laws and regulations have been subject to heightened enforcement activity over the past few years, and significant enforcement activity has been the result of "relators," who serve as whistleblowers by filing complaints in the name of the U.S. (and, if applicable, particular states) under applicable false claim laws. Under the federal False Claims Act, relators can be entitled to receive up to 30% of the total recoveries. Penalties under fraud and abuse laws may be severe, including treble damages and substantial civil penalties under the federal False Claims Act, as well as potential loss of licenses and the ability to participate in federal and state health care programs, criminal penalties, or imposition of a corporate integrity agreement or corporate compliance monitor which could have a material adverse effect on our business. Also, these measures may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. Most states have adopted similar state false claims laws, and these state laws have their own penalties which may be in addition to federal False Claims Act penalties, as well as other fraud and abuse laws. With respect to measures of this type, the U.S. government (among others) has expressed concerns about financial relationships between suppliers on the one

Animal Health
INTERNATIONAL

May 29, 2013

California State Board of Pharmcy
Attn: Jennifer Sevilla
1625 North Market Blvd, Suite N219
Sacramento, CA 95834-1924

RE: File No: CI 2011 52457 / CI 2012 56535

Ms. Sevilla:

In response to the aforementioned citations, please find the payment in the amount of $500 in the settlement of CI 2012 56535.

Please accept the enclosed payment from Animal Health International on Ms. Espinola's behalf, as the alleged violation occurred while she was acting as an employee of Animal Health International.

I trust this will satisfy your request, but please feel free to contact me at the number below if you have any questions or if I can be of any further assistance.

Regards,

Marcus Prochazka
Regulatory Manager
Animal Health International, Inc.
P.O. Box 1240
Greeley, CO 80632
970.378.2012 phone
970.346.2312 fax
marcus.prochazka@animalhealthinternational.com

Animal Health International Inc
(970) 353-2600

Check No: 10125260

Vendor No: 809307
Vendor Name: CALIFORNIA BOARD OF PHARMACY

Check Date: 05/29/2013
Page: 1 of 1

Invoice Number	Invoice Date	Invoice Comments	Gross Amount	Discount	Net Amount
052213CR	05/22/2013		500.00	0.00	500.00
		Check Total............................			$ 500.00

DETACH FROM CHECK AND KEEP FOR YOUR RECORDS

THIS CHECK HAS A COLORED FACE ON WHITE STOCK AND AN ARTIFICIAL WATERMARK ON THE BACK.

Animal Health INTERNATIONAL

usbank
US Bank
235 First Street
Havre MT 59501-3526

93-445
929

Check No: 10125260
Check Date: 05/29/2013

PO BOX 1360 - GREELEY, CO 80632 - (970) 353-2600

PAY TO THE ORDER OF CALIFORNIA BOARD OF PHARMACY $500.00

FIVE HUNDRED & 00/100 XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DOLLARS

CALIFORNIA BOARD OF PHARMACY
1625 NORTH MARKET BLVD #N219
SACRAMENTO CA 95834-1924

[redacted]

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number: CI 2012 56535
Name, License No: GRACIE MARIE ESPINOLA , EXV 20090

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1	Minimum standards for veterinary food-animal drug retailers.	$500.00

CONDUCT:

Gracie Espinola (EXV 20090) was not in compliance with California Code of Regulations, title 16, section 1780.1 (h)(9), which requires labels affixed to a veterinary food-animal drug dispensed to Business and Professions Code section 4041 shall contain the withdrawal time. Specifically, on 1/3/2012, while working at AHI-West (located at 8711 West Doe Avenue, Suite A, Visalia, CA 932910), veterinary retailer designated representative Gracie Espinola furnished RX# BW1728 (Polyflex 25gm) for client JVD with an incorrect label associated with the withdrawal time (missing withhold time of 2 days for milk; label on bottle indicated only withhold time of 6 days for meat). This is a violation of pharmacy law.

CITATION ISSUED ON: April 18, 2013 | TOTAL AMOUNT OF FINE(S): $500.00

PAYMENT OF FINE(S) DUE BY: May 18, 2013

Animal Health INTERNATIONAL

2915 Rocky Mountain Avenue
Suite 400
Loveland, CO 80538
800.203.5620

Animal Health International, Inc. (AHI) Disclosure Statement

a. On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement, a fine, and AHI paid $41,250.

b. On April 18, 2013, Animal Health International, Inc.'s (AHI) Visalia, California Veterinary Food-Animal Drug Retailer license was cited by the California Board of Pharmacy for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

c. On June 18, 2013, Animal Health International, Inc.'s (AHI) Salina, Kansas facility was issued a drug distributor license by the Missouri Division of Professional Regulation. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

d. On August 30, 2013, Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license was cited by the California Board of Pharmacy for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failure to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

e. On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no allegations of misconduct beyond the conduct in Arkansas which led to the non-disciplinary order and fine.

f. In March 2017, Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license was issued a letter of admonishment by the Colorado Board of Pharmacy following allegations that it failed to timely submit an application to the Board detailing a change in designated representative.AHI was required to pay costs associated with the Board's order.

g. On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce veterinary prescription drugs that were misbranded to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

h. On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine in the amount of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Boaz, Alabama wholesale drug distributor license.

i. On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas wholesale drugdistributor license.

j. On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license (#PH32369). This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/4/2013	3/5/2013	FL	Tallahassee	Leon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2012-026145	Florida Department of Business and Professional Regulation (DBPR)

Reason/Charge
Violations of Sections 499.005(22) and 499.005(2)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc

Provide explanation below:

On March 4, 2013, Animal Health International, Inc.'s (AHI) Mayo, Florida Veterinary Prescription Drug Wholesale Distributor license was disciplined by the Florida Department of Business and Professional Regulation (DBPR) related to allegations that AHI failed to report a change of ownership to the DBPR in a timely manner. AHI and the DBRP reached a settlement agreement, a fine, and AHI paid $41,250.

Kelly Kara
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

FILED
Department of Business and Professional Regulation
Deputy Agency Clerk
CLERK Brandon Nichols
Date 3/5/2013
File # 2013-01148

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULAT

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v.

ANIMAL HEALTH INTERNATIONAL, INC.,

Respondent.
_____/

CASE NOs.: 2012-026145
2012-026174
2012-040970
2012-040997

FINAL ORDER

The Department of Business & Professional Regulation (Department), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Animal Health International, Inc., (Respondent) and the Department, attached hereto and incorporated by reference. This final order and settlement agreement are to resolve alleged violations of Section 499.005(22), Florida Statutes, (2010-2012), failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required; and Section 499.005(2), Florida Statutes (2010-2012), the adulteration or misbranding of any drug, device or cosmetic.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department of Business & Professional Regulation as indicated on this Final Order.

DONE and ORDERED this 4th day of March, 2013 in Tallahassee, Florida.

KEN LAWSON, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Reginald D. Dixon
Executive Director
Drugs, Devices and Cosmetics

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been served by regular U.S. Mail this 5th day of March, 2013, to: Animal Health International, Inc.; Attention Lyndee J. Collins, 343 West Main Street, Mayo, Florida 32066.

Brandon M. Nichols
Agency Clerk's Office

cc: Kathryn E. Price
Chief Attorney
Drugs, Devices and Cosmetics
1940 N. Monroe Street
Tallahassee, Florida 32399-1047

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION,

Petitioner,

v.

Case Nos.: 2012-026145
2012-026174
2012-040970
2012-040997

ANIMAL HEALTH INTERNATIONAL, INC.,

Respondent.
_____/

RECEIVED
MAR 04 2013
Drugs, Devices and Cosmetics

SETTLEMENT AGREEMENT

Pursuant to Section 120.57, Florida Statutes, the above named parties hereby enter into this settlement as disposition of the attached Amended Notice of Violation, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1. Animal Health International, Inc. (hereinafter "Animal Health") was issued the attached Amended Notice of Violation (hereafter, "Notice of Violation") for its non-compliance with veterinary prescription drug wholesale distributor permit requirements of the Department.

2. The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 499.001, Florida Statutes.

CONCLUSIONS OF LAW

3. Animal Health, by and through its undersigned officer, admits that it is subject to the provisions of Chapter 499, Florida Statutes, and to the jurisdiction of the Department.

4. Animal Health admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes, but Animal health neither admits nor denies those findings.

SETTLEMENT

5. Animal Health agrees to immediately cease any practices that are in violation of Chapter 499, Florida Statutes.

6. Animal Health agrees to pay a fine of **Forty-one Thousand, Two Hundred Fifty Dollars ($41,250.00)**. Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, C/O Janetta Sampson, Drugs, Devices and Cosmetics, 1940 North Monroe Street, Suite 26A, Tallahassee, FL 32399-1047. Respondent acknowledges that payment is enclosed with this agreement The payment of the settlement amount and execution of this agreement by Respondent are absolute conditions precedent to Petitioner's execution of this agreement. By its acceptance of Respondent's payment and execution of this agreement, Petitioner agrees that all allegations of noncompliance alleged in the Notice of Violation shall be fully, finally, and conclusively resolved.

7. Animal Health affirms that the alleged violations cited in the Notice of Violation have been corrected

8 Animal Health affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted pursuant thereto.

9 It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

10. Animal Health expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of this Settlement Agreement and the final order in which the agreement is incorporated.

11. Each party waives the right to seek any attorney's fees or costs from the Department in connection with this proceeding.

ANIMAL HEALTH INTERNATIONAL, INC.

By: _____

Name: David R. Wagley

Title: Executive VP and CFO

Date: 02/26/2013

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Name: REGINALD D. DIXON

Title: DIRECTOR

Date: 3/4/13

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/18/2013		CA	Sacramento	Sacramento

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2012 56535	California State Board of Pharmacy

Reason/Charge
Violation of California Code of Regulations, title 16, section 1780.1 (h)(9)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Gracie Marie Espinola	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On April 18, 2013, Animal Health International, Inc.'s (AHI) Visalia, California Veterinary FoodAnimal Drug Retailer license was cited by the California Board of Pharmacy for an alleged failure to affix labels to a product dispensed in California. AHI paid a fine of $500.

Kelly Karr
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

April 18, 2013

DATED MATERIAL ENCLOSED

GRACIE MARIE ESPINOLA
[redacted] WEST OWENS AVE
TULARE, CA 93274

RE: CI 2012 56535
GRACIE MARIE ESPINOLA
EXV 20090

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- May 18, 2013: Unless the Citation is contested payment of fine(s) must be received by the Board.
- May 02, 2013: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- May 18, 2013: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Jennifer Sevilla, Enforcement Analyst at (916) 574-7925.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

Attachments

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
6/18/2013	6/18/2013	MO	Jefferson City	Cole

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2012-007179	Missouri Board of Pharmacy

Reason/Charge
Violations of Section 324.038, RSMo; Section 338.055.1 and .2(6)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Icn.

Provide explanation below:

On June 18, 2013, Animal Health International, Inc.'s (AHI) Salina, Kansas facility was issued a drug distributor license by the Missouri Division of Professional Regulation. The license was issued subject to probation due to allegations that this entity distributed legend drugs in Missouri without being licensed to do so. On June 17, 2015, the probation was terminated.

Kelly Kaza
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

Regulatory Licensing Manager

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rachers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grimston
Executive Director
www.pr.mo.gov/pharmacists
e-mail: MissouriBOP@pr.mo.gov

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7196 9008 9040 1809 0513

June 20, 2013

Stephen B. Leinenbach
Senior VP of Operations
Animal Health International, Inc.
1449A W. Old Highway 40
Salina, KS 67401

Dear Mr. Leinenbach:

I am writing to you as a representative of the Missouri Board of Pharmacy ("Board"). At the April 2013 meeting, the Board reviewed your application for licensure as a drug distributor in Missouri for your facility located at 1449A W. Old Highway 40, Salina, Kansas.

After careful consideration, it was the Board's decision to issue Animal Health International, Inc. a restricted drug distributor license pursuant to Section 324.038, RSMo, based on violation of Section 338.055.1 and .2(6), RSMo. A copy of the Board's Order containing the restrictions that have been imposed on your license is enclosed. Your permanent Missouri drug distributor license, numbered 2013019603, that was issued June 18, 2013, with restrictions is enclosed. Please review the enclosed Order carefully. **It is your responsibility to comply with all terms of this Order**. If you have questions about any portion of the terms and conditions, contact this office.

Enclosed are two copies of the Pharmacy and Drug Distributor Report of Discipline Compliance form for use in submitting the six-month reports required by the Order. The first report will be due July 1 and each January and July following through the ending date of probation. This form may be copied as needed for future use, and is available on our website, www.pr.mo.gov/pharmacists, click Applications and Forms, Miscellaneous.

If you wish to contest the Board's decision, you must file a written complaint with the Administrative Hearing Commission within thirty (30) days following delivery or certified mailing of this letter and Order. The written request should be addressed to the Administrative Hearing

Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30)-day period, the right to seek review of the Board's decision shall will be considered waived.

Sincerely,

Tammy Siebert

TAMMY SIEBERT
EXECUTIVE I

Enclosures

cc: Jolene Goddard, Manager-in-Charge

BEFORE THE
MISSOURI BOARD OF PHARMACY
STATE OF MISSOURI

IN RE:)
)
ANIMAL HEALTH INTERNATIONAL, INC.) Case #2012-007179

ORDER OF THE MISSOURI BOARD OF PHARMACY ISSUING ANIMAL HEALTH INTERNATIONAL, INC. A DRUG DISTRIBUTOR LICENSE SUBJECT TO PROBATION

Comes now the Missouri Board of Pharmacy ("Board") and issues its ORDER granting a PROBATED drug distributor license, license number 2013019603, to Animal Health International, Inc. ("Animal Health") pursuant to the provisions of Section 324.038, RSMo. As set forth in Section 324.038, RSMo, Animal Health may submit a written request for a hearing to the Administrative Hearing Commission seeking review of the Board's decision to issue a probated license to Animal Health. Such written request must be submitted to the Administrative Hearing Commission within thirty (30) days of issuance of this Order. The written request should be addressed to the Administrative Hearing Commission, P.O. Box 1557, Truman Building Room 640, Jefferson City, MO 65102-1557. If no written request for review is received by the Administrative Hearing Commission within the thirty (30) day period, the right to seek review of the Board's decision shall be waived.

The disciplinary period shall become effective immediately upon issuance of Animal Health's license as a drug distributor. Should Animal Health file a written request for review of this Order, the terms and conditions of the Order shall remain in force and effect unless and/or until such time as the Administrative Hearing Commission issues an order contrary to this Order.

FINDINGS OF FACT

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo, for the purpose of executing and enforcing provisions of Chapter 338, RSMo.

2. Animal Health filed an application for a drug distributor license with the Board on November 5, 2012. This probated drug distributor license is for the facility owned by Animal Health at 1449A N. Old Highway 40, Salina, Kansas 67401. The Board had previously issued Walco International, Inc. a drug distributor license number 2003031150, for this location.

3. Animal Health shipped legend drugs from its current location from June 11, 2011, through January 22, 2013, without being licensed to do so. Animal Health's records reflect that it delivered at least 869 orders of legend drugs within Missouri without a valid drug distributor license.

4. Based on information received by the Board, pursuant to Section 338.055, RSMo, the Board concluded Animal Health engaged in conduct which would be grounds for denying Animal Health a license, or if currently licensed by the Board, disciplinary action by the Board against its drug distributor license.

CONCLUSIONS OF LAW

5. Animal Health's conduct as alleged above is cause for the Board to deny Animal Health a license to be a drug distributor pursuant to Section 338.055.1 and .2, RSMo, which states in pertinent parts:

> 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621, RSMo.
>
> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

6. Section 324.038, RSMo, provides in pertinent part:

> 1. Whenever a board within the division of professional registration, including the division itself when so empowered, may refuse to issue a license for reasons which also serve as a basis for filing a complaint with the administrative hearing commission seeking disciplinary action against a holder of a license, the board, as an alternative to refusing to issue a license, may, at its discretion, issue to an applicant a license subject to probation.

7. The Board hereby issues this ORDER in lieu of denial of Animal Health's request for a drug distributor license in Missouri pursuant to Section 324.038, RSMo.

8. Pursuant to the provisions of Section 324.038, RSMo, the Board hereby issues drug distributor license number 2013019603 to Animal Health in lieu of denial of Animal Health's request for a license to practice as a drug distributor in Missouri. License number 2013019603 is issued subject to the terms and conditions set forth herein below.

ORDER

Based on the foregoing and in lieu of denying Animal Health International, Inc., a drug distributor license, the Board hereby issues Animal Health International, Inc. a license subject to PROBATION for two (2) years (hereinafter "disciplinary period"). The terms of the disciplinary period shall be:

1. Respondent shall pay all required fees for licensing to the Board and shall renew its drug distributor license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its drug distributor license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

4. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Order/Agreement becomes effective, stating truthfully whether or not he/she has complied with all terms and conditions of his/her disciplinary order.

5. Respondent shall make a representative of the drug distributor available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

6. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Order.

7. The Board of Pharmacy will maintain this Order as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

8. Upon the expiration of the disciplinary period, Animal Health's license as a drug distributor shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that Animal Health has violated any term or

condition of this Order, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Animal Health 's drug distributor license.

9. No order shall be entered by the Board pursuant to the preceding paragraph of this Order without notice and an opportunity for a hearing before the Board in accordance with provisions of Chapter 536, RSMo.

10. If the Board determines that Animal Health has violated a term or condition of this Order, which violation would be actionable in a proceeding before the Administrative Hearing Commission or the Circuit Court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Order in its determination of appropriate legal actions concerning that violation.

SO ORDERED this 18th day of June, 2013

MISSOURI BOARD OF PHARMACY

KIMBERLY A. GRINSTON
EXECUTIVE DIRECTOR

MAILING ADDRESS:
MISSOURI BOARD OF PHARMACY
P.O. BOX 625
JEFFERSON CITY, MO 65102
(573) 751-9056
(573) 526-3464 (FAX)
E-MAIL: COMPLIANCE@PR.MO.GOV
DELIVERY ADDRESS:
3605 MISSOURI BOULEVARD
JEFFERSON CITY, MO 65109

STATE OF MISSOURI
DIVISION OF PROFESSIONAL REGISTRATION

PHARMACY AND DRUG DISTRIBUTOR REPORT OF DISCIPLINE COMPLIANCE

INSTRUCTIONS:

1. This form MUST be completed/signed by the sole proprietor, partner or corporate officer of the pharmacy/drug distributor.
2. Fill in all blanks and answer all questions completely and accurately.

LICENSEE INFORMATION

PHARMACY/DRUG DISTRIBUTOR NAME	LICENSE NO.	DATE
PHARMACY/DRUG DISTRIBUTOR ADDRESS (STREET, CITY, STATE, ZIP CODE)		CURRENT TELEPHONE NUMBER
PHARMACY/DRUG DISTRIBUTOR E-MAIL ADDRESS		ALTERNATE TELEPHONE NUMBER
PHARMACIST/MANAGER-IN-CHARGE NAME		LICENSE NO. (IF APPLICABLE)

MISSOURI LICENSE STATUS IS	IF "EXPIRED," DATE LICENSE EXPIRED
☐ ACTIVE ☐ INACTIVE ☐ EXPIRED	
HAS THIS PHARMACY/DRUG DISTRIBUTOR CHANGED LOCATIONS IN THE PAST SIX (6) MONTHS? ☐ YES ☐ NO	IF YES, WAS THE CHANGE OF LOCATION REPORTED TO THE BOARD OFFICE? ☐ YES ☐ NO

HAS THIS PHARMACY/DRUG DISTRIBUTOR FILED ANY DEA OR BNDD LOSS REPORTS IN THE PAST SIX (6) MONTHS?
☐ YES ☐ NO (IF YES, ATTACH COPIES TO THIS REPORT)

THE FOLLOWING IS A CURRENT LIST OF PARTNERS/CORPORATE OFFICERS OF THIS PHARMACY/DRUG DISTRIBUTOR (ATTACH SEPARATE SHEET IF NECESSARY)

NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE
NAME	TITLE

THE FOLLOWING IS A LIST OF ALL FULL-TIME AND PART-TIME LICENSED/REGISTERED PHARMACISTS, INTERNS, TECHNICIANS PERFORMING DUTIES AT THIS PHARMACY/DRUG DISTRIBUTOR (ATTACH SEPARATE SHEET IF NECESSARY)

NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION
NAME	LICENSE NUMBER	POSITION

COMPLIANCE STATEMENT

DATES OF MISSOURI DISCIPLINE

PROBATION _____ TO _____

HAVE YOU REVIEWED THE PHARMACY/DRUG DISTRIBUTOR'S DISCIPLINARY ORDER/SETTLEMENT AGREEMENT IN THE LAST SIX (6) MONTHS?

☐ YES ☐ NO

I/WE HAVE DONE THE FOLLOWING TO COMPLY WITH EACH REQUIREMENT OF THE DISCIPLINARY ORDER/SETTLEMENT AGREEMENT. (ATTACH SEPARATE SHEET IF NECESSARY)

CONSULTANT INFORMATION

If a consultant is a requirement of your discipline, answer the following.

NAME OF CONSULTANT	CONSULTANT TELEPHONE NUMBER

ADDRESS OF CONSULTANT

DATE OF LAST VISIT	DATE OF NEXT VISIT	CONSULTANT E-MAIL ADDRESS

LIST ANY CHANGE YOU HAVE MADE TO YOUR OPERATION BASED ON YOUR CONSULTANT'S LAST REPORT (ATTACH ADDITIONAL SHEETS IF NECESSARY).

By my signature below, I hereby attest that I am a partner, corporate officer, or the sole proprietor of the pharmacy/drug distributor named in this compliance report, and the report has been completed knowingly, truthfully and completely, without omissions. I understand that this pharmacy/drug distributor must comply with federal and state laws and regulations, including that the facility shall maintain a pharmacist/manager-in-charge for the facility and such pharmacy/drug distributor shall be conducted and operated in full compliance with state and federal laws and regulations. All the information contained in the report and any attachments hereto are true and correct to my best knowledge and belief. I understand that any false statement or material omission may result in discipline or further penalty under state law. I hereby certify under the penalty of perjury that the above statement, as well as all information provided herein are true and correct.

SIGNATURE OF SOLE PROPRIETOR, PARTNER OR CORPORATE OFFICER	DATE

PRINT NAME	TITLE

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Kathleen (Katie) Steele Danner, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
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800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists
email: MissouriBOP@pr.mo.gov

July 7, 2015

Stephen Leinenbach
Senior VP of Operations
Animal Health International, Inc.
PO Box 1240
Greeley CO 80632

Dear Mr. Leinenbach:

This is official notification that Animal Health International Inc., permit #2013019603 has completed the terms of probation with the Missouri Board of Pharmacy as of June 17, 2015.

If you have any questions, or if we can be of assistance in the future, feel free to contact this office. Thank you for complying.

Sincerely,

Jennifer Luebbert
Compliance Coordinator
Missouri Board of Pharmacy

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
8/30/2013	8/30/2013	CA	Sacramento	Sacramento

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2013 58076	California Board of Pharmacy

Reason/Charge
Not in compliance with CCR, Title 16, § 1780 and Bus and Prof Code 4053

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On August 30, 2013, Animal Health International, Inc.'s (AHI) Ceres, California Veterinary Food Animal Drug Retailer license was cited by the California Board of Pharmacy for alleged violations of allowing a non-pharmacist to receive an oral order from a veterinarian, furnishing medications without a valid prescription, and failure to comply with labeling requirements. AHI paid a fine of $3,500. Two AHI employees were also cited and fined a total of $3,000.

Kelley Ike
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

COPY

CITATION AND FINE

Citation Number	Name, License No
CI 2013 58076	JOSEPH E SHACKELFORD , EXV 16742

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1 subd. (d)	Only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian	$1,000.00
CCR, Title 16, § 1780.1 subd. (h)	Labels affixed to a veterinary food-animal drug...label requirements	$500.00
Bus. & Prof. Code § 4053 subd. (d)	Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs	$1,000.00

CONDUCT:

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with California Code of Regulations, section 1780.1(d) which states only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian. Specifically, on 3/27/12, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were receiving oral orders from veterinarians. This was a violation of pharmacy law.

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with California Code of Regulations, section 1780.1(h)(2)(15) which states labels affixed to a veterinary food-animal drug shall contain the manufacturer of the drug and the manufacturer's expiration date. Specifically, on 3/27/23, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was noted the manufacturer of the drug or the expiration date was not indicated on the prescription labels. This was a violation of pharmacy law.

Vet Retailer Exemptee, Joseph Shackelford was not in compliance with Business and Professions Code, Section 4053(d) which states only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs. Specifically, on 3/27/12, during an inspection of Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Joseph Shackelford was vet retailer exemptee, EXV 16742, it was acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were preparing and affixing the labels for food-animal drugs. This was a violation of pharmacy law.

CITATION ISSUED ON: August 30, 2013 TOTAL AMOUNT OF FINE(S): $2,500.00

PAYMENT OF FINE(S) DUE BY: September 29, 2013

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2013 58075	MARK ALDAX , EXV 15005

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4160 subd. (d)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)	Furnishing dangerous drugs without a prescription	$500.00

CONDUCT:

Vet Retailer Exemptee, Mark Aldax was not in compliance with Business and Professions Code, section 4059(a) which states a person cannot furnish any dangerous drug, except upon the prescription of a physician, dentist, veterinarian. Specifically, on 6/20/12, 7/26/12, and 12/19/12 Animal Health International, located at 1908 Rockefeller Drive Ceres, CA 95307, where Mark Aldax, EXV 15005, was vet retailer exemptee, furnished several different dangerous drugs including long acting antibiotics without authorization from Dr. Grant Miller. This was a violation of pharmacy law.

CITATION ISSUED ON: August 30, 2013 **TOTAL AMOUNT OF FINE(S): $500.00**

PAYMENT OF FINE(S) DUE BY: September 29, 2013

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number **Name, License No**
CI 2012 53842 **ANIMAL HEALTH INTERNATIONAL INC, VET 144**

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1780.1 subd. (d)	Only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian	$1,000.00
CCR, Title 16, § 1780.1 subd. (h)	Labels affixed to a veterinary food-animal drug...label requirements	$500.00
Bus. & Prof. Code § 4059 subd. (a)	Furnishing dangerous drugs without a prescription	$1,000.00
Bus. & Prof. Code § 4053 subd. (d)	Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs	$1,000.00

CONDUCT:

Animal Health International (Vet 144) was not in compliance with California Code of Regulations, section 1780.1(d) which states only a pharmacist or the vet retailer exemptee may receive an oral order for a veterinary food-animal drug from the veterinarian. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were receiving oral orders from veterinarians. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with California Code of Regulations, section 1780.1(h)(2)(15) which states labels affixed to a veterinary food-animal drug shall contain the manufacturer of the drug and the manufacturer's expiration date. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, did not have the manufacturer of the drug or the expiration date indicated on the prescription labels. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with Business and Professions Code, section 4059(a) which states a person cannot furnish any dangerous drug, except upon the prescription of a physician, dentist, veterinarian. Specifically, on 6/20/12, 7/26/12, and 12/19/12 Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, furnished several dangerous drugs including long acting antibiotics without authorization from Dr. Grant Miller. This was a violation of pharmacy law.

Animal Health International (Vet 144) was not in compliance with Business and Professions Code, Section 4053(d) which states only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs. Specifically, on 3/27/13, at the time of inspection, Animal Health International located at 1908 Rockefeller Drive Ceres, CA 95307, acknowledged, many employees other than a vet retailer exemptee (designated representative) or pharmacist were preparing and affixing the labels for food-animal drugs. This was a violation of pharmacy law.

CITATION ISSUED ON: August 30, 2013 **TOTAL AMOUNT OF FINE(S): $3,500.00**

PAYMENT OF FINE(S) DUE BY: September 29, 2013

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/13/2017	3/13/2017	AL	Birmingham	Jefferson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
17-L-0003	Alabama Board of Pharmacy

Reason/Charge
Violation of Alabama Pharmacy Practice Act

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On March 13, 2017, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama Board of Pharmacy in which AHI agreed to pay a fine of $1,000 following allegations that AHI's Manchester, Iowa pharmacy had violated Alabama law by being disciplined by the Arkansas Board of Pharmacy. AHI had entered into a non-disciplinary agreement with the Arkansas Board of Pharmacy following allegations that it had not notified the Arkansas Board of a change of ownership in a timely manner and paid a non-disciplinary fine of $2,500 to the Arkansas Board. The Alabama Board made no allegations of misconduct beyond the conduct in Arkansas which led to the non-disciplinary order and fine.

Kelly Haren
Original Signature (electronic, copies or stamps not accepted)

11/27/23
Date

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Non-Resident Pharmacy Permit Number: 114325	)	**CASE NO: 17-L-0003**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. ("Animal Health") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Animal Health through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Animal Health has violated the provisions of law based upon the conduct set out in Counts One and Two of the Statement. Count Three of the Statement shall be dismissed with prejudice.

2. Animal Health shall pay an administrative fine in the amount of One Thousand Dollars ($1,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.

3. Animal Health expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform

Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Animal Health International, Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Animal Health hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Animal Health acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Animal Health's permit, including, but not limited to revocation.

6. Animal Health acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Animal Health acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 3rd of March, 2017.

ANIMAL HEALTH INTERNATIONAL, INC.

BY: _____

ITS: VP, Regulatory Affairs

_____

Christopher Bottcher, attorney for Animal Health International, Inc.

DONE this the 13th of March, 2017.

ALABAMA STATE BOARD OF PHARMACY

By: _____

Buddy Bunch, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & WILSON, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/13/2017	3/20/2017	CO		Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2016-4043	Colorado Board of Pharmacy

Reason/Charge
Violation of §12-42.5-123(1)(l)-(III), C.R.S.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

In March 2017, Animal Health International, Inc.'s (AHI) Greeley, Colorado wholesale distributor license was issued a letter of admonishment by the Colorado Board of Pharmacy following allegations that it failed to timely submit an application to the Board detailing a change in designated representative.AHI was required to pay costs associated with the Board's order.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2016-4043

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF ANIMAL HEALTH INTERNATIONAL, INC., REGISTRATION NO. WHI 6020,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Animal Health International, Inc. ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2016-4043, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2016).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 8, 2006, being issued registration number WHI 6020, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 620 "O" Street, Greeley, CO 80632.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, approximately 240 days transpired between December 1, 2015, the date the previous designated representative ceased the position, and August 4, 2016, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet admits that its conduct, as set forth above, constitutes a violation of §12-42.5-123(1)(c)(I)-(III), C.R.S., and Rules 15.01.11(b) and 15.01.14(c) and provides grounds for disciplinary action against Respondent Outlet's Colorado registration as a wholesaler.

TERMS OF DISCIPLINE

8. **Letter of Admonition.** This Final Agency Order shall constitute a Letter of Admonition as set forth in §12-42.5-124(6)(b) and (c), C.R.S. The Board hereby admonishes Respondent Outlet for the acts and omissions described in paragraphs 5-7 above.

9. **Waiver of Right to Contest.** By entering into this Final Agency Order, Respondent Outlet agrees to waive the right provided by §12-42.5-124(6)(b) and (c), C.R.S., to contest this Letter of Admonition.

10. **Other Requirements.** Through its undersigned Authorized Representative, Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges.

    c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

17. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

_____ Dated: 3/20/2017
Authorized Representative / Title

Subscribed and sworn to before me in the County of Weld, State of Colorado, this 20th day of March, 2017, by David R. Wagley, authorized representative of Animal Health International, Inc.

My commission expires: Jan 5, 2019 _____
Notary Public

ISABELLA NOVAK
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID # 20154000145
MY COMMISSION EXPIRES JANUARY 05, 2019

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 23rd day of March, 2017.

State Board of Pharmacy

BY: _____
Chris Gassen
Interim Program Director

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within fully executed **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 23rd day of March 2017, addressed as follows:

By electronic mail to Respondent:
Animal Health International, Inc.
Attn: Marcus Prochazka, Regulatory Mngr.
620 "O" Street
Greeley, CO 80632
Email: Marcus.Prochazka@animalhealthinternational.com

Agent of the Board

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/14/2020		VA	Abingdon	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
DVAW120CR00007-001	United States District Court, Western District of Virginia Abingdon

Reason/Charge
Violation of Title 21, US Code, Sections 331(a), 333(a)(1), and (352)(f)(l)

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On February 14, 2020, Animal Health International, Inc. (AHI) entered a plea of guilty for introducing into interstate commerce veterinary prescription drugs that were misbranded to persons who were not licensed to possess or distribute veterinary prescription drugs on the order of a veterinarian who was not properly licensed in Virginia. AHI Paid a fine of $5,000,000.

Kelley Kam
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

UNITED STATES DISTRICT COURT

Western District of Virginia

UNITED STATES OF AMERICA
V.
ANIMAL HEALTH INTERNATIONAL, INC.

JUDGMENT IN A CRIMINAL CASE
(For Organizational Defendants)
CASE NUMBER: DVAW120CR000007-001
CASE NUMBER:
Amy J. Conway-Hatcher, Kyle A. Clark
Defendant Organization's Attorney

THE DEFENDANT ORGANIZATION:

☒ pleaded guilty to count(s) Count 1 of Information

☐ pleaded nolo contendere to count(s) _____ which was accepted by the court.

☐ was found guilty on count(s) _____ after a plea of not guilty.

The organizational defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
21 U.S.C. § 331(a), 333(a)(1), and 352(f)(1)	Introduction of Misbranded Drugs into Interstate Commerce	4/2015	1

The defendant organization is sentenced as provided in pages 2 through 8 of this judgment.

☐ The defendant organization has been found not guilty on count(s) _____

☐ Count(s) _____ ☐ is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant organization must notify the United States attorney for this district within 30 days of any change of name, principal business address, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant organization must notify the court and United States attorney of material changes in economic circumstances.

Defendant Organization's Federal Employer I.D. No.: 84-0575063

Defendant Organization's Principal Business Address:

822 7th Street
Suite 610
Greeley, CO 80631

Defendant Organization's Mailing Address:

822 7th Street
Suite 610
Greeley, CO 80631

May 4, 2020
Date of Imposition of Judgment

Signature of Judge

James P. Jones, United States District Judge
Name and Title of Judge

5/4/2020
Date

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

PROBATION

The defendant organization is hereby sentenced to probation for a term of :

One (1) year.

The defendant organization shall not commit another federal, state or local crime.

If this judgment imposes a fine or a restitution obligation, it is a condition of probation that the defendant organization pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant organization must comply with the standard conditions that have been adopted by this court as well as any additional conditions on the attached page (if indicated below).

STANDARD CONDITIONS OF SUPERVISION

1) within thirty days from the date of this judgment, the defendant organization shall designate an official of the organization to act as the organization's representative and to be the primary contact with the probation officer;

2) the defendant organization shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;

3) the defendant organization shall notify the probation officer ten days prior to any change in principal business or mailing address;

4) the defendant organization shall permit a probation officer to visit the organization at any of its operating business sites;

5) the defendant organization shall notify the probation officer within seventy-two hours of any criminal prosecution, major civil litigation, or administrative proceeding against the organization;

6) the defendant organization shall not dissolve, change its name, or change the name under which it does business unless this judgment and all criminal monetary penalties imposed by this court are either fully satisfied or are equally enforceable against the defendant's successors or assignees; and

7) the defendant organization shall not waste, nor without permission of the probation officer, sell, assign, or transfer assets.

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

SPECIAL CONDITIONS OF SUPERVISION

While on probation, the defendant:

(1) Must comply with the requirements contained in the Plea Agreement and the Non-Prosecution Agreement of Defendant's parent corporation.

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

CRIMINAL MONETARY PENALTIES

The defendant organization must pay the following total criminal monetary penalties under the schedule of payments on Sheet 4.

	Assessment	Fine	Restitution
TOTALS	$ 125.00	$ 5,000,000.00	$

☐ The determination of restitution is deferred until _____ . An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

☐ The defendant organization shall make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant organization makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage

TOTALS	$0.00	$0.00

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant organization shall pay interest on restitution or a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 4 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant organization does not have the ability to pay interest, and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, I
CASE NUMBER: DVAW120CR000007-001

ADDITIONAL TERMS FOR CRIMINAL MONETARY PENALTIES

The defendant must pay $1,000,000.00 to the Virginia Department of Health Professions in recognition of direct assistance provided by DHP to the United States during the investigation.

AO 245E (Rev. 12/03 - VAW Additions 3/04) Judgment in a Criminal Case for Organizational Defendants
Sheet 4 - Schedule of Payments

DEFENDANT ORGANIZATION: ANIMAL HEALTH INTERNATIONAL, IN
CASE NUMBER: DVAW120CR000007-001

SCHEDULE OF PAYMENTS

Having assessed the organization's ability to pay, payment of the total criminal monetary penalties are due as follows:

A ☐ Lump sum payment of $ _____ due immediately, balance due

☐ not later than _____ , or
☐ in accordance with ☐ C or ☐ D below; or

B ☐ Payment to begin immediately (may be combined with ☐ C or ☐ D below); or

C ☐ Payment in _____ (e.g., equal, weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ (e.g., 30 or 60 days) after the date of this judgment; or

D ☒ Special instructions regarding the payment of criminal monetary penalties:

All amounts have been paid in full.

All criminal monetary penalties are made to the clerk of the court.

The defendant organization shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

☐ The defendant organization shall pay the cost of prosecution.

☐ The defendant organization shall pay the following court cost(s):

☒ The defendant organization shall forfeit the defendant organization's interest in the following property to the United States:
See attached Agreed Order of Forfeiture.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
1095
FILED

FEB 14 2020

JULIA C. DUDLEY, CLERK
BY: DEPUTY CLERK

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON

UNITED STATES OF AMERICA	)	
	)	**Criminal No.** 1:20CR00007
v.	)	
	)	
ANIMAL HEALTH INTERNATIONAL, INC.	)	

AGREED ORDER OF FORFEITURE

IT IS HEREBY ORDERED THAT:

A. Pursuant to Rule 32.2(b)(1)(A) of the Federal Rules of Criminal Procedure, the evidence of record and the guilty plea to Count One of the Information, misbranding a drug, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(f)(1), the defendant shall forfeit to the United States quantities of prescription veterinary drugs that were misbranded when introduced into interstate commerce and/or when being held for sale in interstate commerce, pursuant to 21 U.S. C. § 334 and 28 U.S.C. § 2461.

B. Pursuant to the defendant's plea agreement, because the above-described forfeitable property, as a result of the defendant's acts, has been transferred or sold to third parties and cannot be located upon the exercise of due diligence, a money judgment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) is hereby entered against the defendant as a substitute asset pursuant to 21 U.S.C. § 853(p).

C. On or before 7 days from the date of entry of a guilty plea, the defendant will voluntarily remit payment in the amount of $46,802,203 (forty-six million eight hundred two thousand two hundred three dollars) in satisfaction of the money judgment by remitting certified funds made payable to the U.S. Marshals Service, Asset Forfeiture Unit, 247 Federal Building, 210 Franklin Road, S.W., Roanoke, Virginia 24011.

D. As payments are voluntarily being remitted to the United States, notice and publication are not required.

E. The Court shall retain jurisdiction to enforce this Order, and to amend it as necessary, pursuant to Fed. R. Crim. P. 32.2(e).

F. Pursuant to Fed. R. Crim. P. 32.2(b)(4), this Order of Forfeiture shall become final as to the defendant upon entry, and shall be made a part of the sentence and included in the judgment.

ENTERED THIS 14 DAY OF Feb., 2020.

UNITED STATES DISTRICT JUDGE

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2020	7/20/2020	AL	Birmingham	Birmingham

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
20-L-0045	Alabama Board of Pharmacy

Reason/Charge
Violation of Alabama Pharmacy Practice Act

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health international, Inc.	N/A

Name of Business/Industry/Entity
Animal Health international, Inc.

Provide explanation below:

On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine in the amount of $2,000. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Boaz, Alabama wholesale drug distributor license.

Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

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IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
ANIMAL HEALTH INTERNATIONAL, INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Wholesaler	)	**CASE NO: 20-L-0045**
Permit Number: 195552	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. (hereinafter referred to as "AHI ") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and AHI, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that AHI violated the applicable provisions based upon the conduct set out in Count One of the Statement.

2. AHI shall pay to the Board an administrative fine in the amount of Two Thousand Five Hundred dollars ($2,500.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and AHI shall not attempt to discharge the same in any bankruptcy proceeding.

3. That AHI expressly waives its rights pursuant to the Alabama Pharmacy

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Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. AHI further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, AHI hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That AHI agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That AHI acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. AHI acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

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DONE this the 17th day of July, 2020.

Animal Health International, Inc.

By: _____
Its: Secretary

Edward D. Rickert

Edward D. Rickert, Attorney for Animal Health International, Inc.

DONE this the 20 day of JULY, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Ralph E. Sorrell
Ralph E. Sorrell, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

DocuSign Envelope ID: 6941F90E-B5DB-4D8E-9F2C-0594F5D67209

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Wholesaler Permit Number: 195552	)	**CASE NO: 20-L-0045**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Animal Health International, Inc.
1202 Esi Drive
Springdale, Arizona 72764

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 23, 2020 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Animal Health International, Inc. (AHI) as a Wholesaler should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that AHI has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

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(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your Plea Agreement dated February 13, 2020 in a case styled United States of America v Animal Health International, Inc. in the United States District Court for the Western District of Virginia, Criminal Case No. 1:20-cv-00007. A copy of the Plea Agreement

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and Information referenced in the Plea Agreement are attached hereto collectively as Exhibit "A".

The Board alleges that each act of misbranding as described in Exhibit "A" is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 24th day of April, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/20/2020	7/20/2020	AL	Birmingham	Birmingham

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
20-L-0046	Alabama Board of Pharmacy

Reason/Charge
Violations of the Code of Alabama (1975) §34-23-32, §34-23-32.1, 34-23-92(11) and (12), §41-22-12

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health international, Inc.	N/A

Name of Business/Industry/Entity
Animal Health international, Inc.

Provide explanation below:

On July 20th, 2020, Animal Health International, Inc. (AHI) entered into an agreement with the Alabama State Board of Pharmacy in which AHI agreed to pay an administrative fine of $2,500. This agreement was related to the Alabama Board's investigation following AHI's criminal conviction in the United States District Court for the Western District of Virginia and did not involve new conduct. The specific facility subject to discipline was AHI's Springdale, Arkansas wholesale drugdistributor license.

Kelly Kan
Original Signature (electronic, copies or stamps not accepted)

11/17/23
Date

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Wholesaler Permit Number: 400357	)	**CASE NO: 20-L-0046**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Animal Health International, Inc. (hereinafter referred to as "AHI ") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and AHI, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that AHI violated the applicable provisions based upon the conduct set out in Count One of the Statement.

2. AHI shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and AHI shall not attempt to discharge the same in any bankruptcy proceeding.

3. That AHI expressly waives its rights pursuant to the Alabama Pharmacy

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Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. AHI further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, AHI hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That AHI agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That AHI acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. AHI acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

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DONE this the 17th day of July, 2020.

Animal Health International, Inc.

By: _____
Its: Secretary

Edward D. Rickert

Edward D. Rickert, Attorney for Animal Health International, Inc.

DONE this the 20 day of JULY, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Ralph E. Sorrell
Ralph E. Sorrell, R.Ph., President

By: _____
James S. Ward
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
ANIMAL HEALTH INTERNATIONAL, INC.	)	
	)	
Wholesaler Permit Number: 400357	)	**CASE NO: 20-L-0046**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Animal Health International, Inc.
990 River Oaks Road
Boaz, Alabama 35957

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 23, 2020 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Animal Health International, Inc. (AHI) as a Wholesaler should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that AHI has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

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(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your Plea Agreement dated February 13, 2020 in a case styled United States of America v Animal Health International, Inc. in the United States District Court for the Western District of Virginia, Criminal Case No. 1:20-cv-00007. A copy of the Plea Agreement

DocuSign Envelope ID: 19CCC44D-0050-444F-9130-44A8342B4122

and Information referenced in the Plea Agreement are attached hereto collectively as Exhibit "A".

The Board alleges that each act of misbranding as described in Exhibit "A" is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 24th day of April, 2020.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/15/2022	12/15/2022	FL	Tallahassee	Leon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-39162	Florida State Board of Pharmacy

Reason/Charge
Violations of Florida Statutes (2021) Section 20.43 and chapters 456 and 465

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Animal Health International, Inc.	N/A

Name of Business/Industry/Entity
Animal Health International, Inc.

Provide explanation below:

On December 15, 2022, Animal Health International, Inc. (AHI) entered into an agreement with the Florida State Board of Pharmacy in which AHI agreed to pay an administrative fine of $3,500 against the Wolcott, IN pharmacy license (#PH32369). This agreement was related to the Florida Board's investigation following AHI's criminal conviction on February 14, 2020, in the United States District Court for the Western District of Virginia and did not involve new conduct.

Kelly Kanz

Original Signature (electronic, copies or stamps not accepted)

11/17/23

Date

Final Order No. DOH-22-1556 -MQA
FILED DATE - DEC 28 2022
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH, PETITIONER, v. ANIMAL HEALTH INTERNATIONAL, INC. RESPONDENT.	CASE NO.: LICENSE NO.:	2021-39162 PH 32369

FINAL ORDER
APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to section 120.57(4), *Florida Statutes*, on December 15, 2022, at a duly-noticed public meeting held in Orlando, Florida, for consideration of a Settlement Agreement (hereinafter "Settlement Agreement" and attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby **ORDERED AND ADJUDGED:**

1. The Settlement Agreement as submitted is hereby approved, adopted, and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

2. The agreed amount of Costs in this case are $650.11 which shall be paid in the manner outlined in the incorporated Settlement Agreement.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

[SIGNATURE BLOCK ON FOLLOWING PAGE]

DONE AND ORDERED this 28th day of December, 2022.

BOARD OF PHARMACY

GM Mills for
Jessica L. Sapp, Executive Director
On Behalf of David Wright, BPharm, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to **Animal Health International, Inc.** at 2915 Rocky Mountain Avenue, Suite 400, Loveland, CO 80538 and 9146 West Wolcott Industrial Parkway, Wolcott, IN 47995; by electronic mail to **Kara H. Aikens**, Assistant Attorney General, Office of the Attorney General, at kara.aikens@myfloridalegal.com; and by electronic mail to **Alejandro Camacho,** Assistant General Counsel, Prosecution Services Unit, at alejandro.camacho@flhealth.gov, and **Edward Rickert**, Counsel to Respondent, at edward.richert@quarles.com this 28th day of December, 2022.

Anna L. Cannaday
DEPUTY AGENCY CLERK

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2021-39162**

ANIMAL HEALTH INTERNATIONAL, INC.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy ("Board") as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **Animal Health International, Inc.**, was a permitted **non-resident pharmacy** in the state of Florida, having been issued permit number **PH29236**. Respondent's mailing address of record is 2915 Rocky Mountain Avenue, Ste. 400, Loveland, Colorado 80538.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health ("Department") and properly served upon Respondent, with violations of Chapters 456 and/or 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that they are subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Fine**- The Board of Pharmacy shall impose an administrative fine of **THREE THOUSAND FIVE HUNDRED DOLLARS ($3,500.00).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

2. **Costs**- The Board of Pharmacy shall impose the total administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FOUR HUNDRED DOLLARS ($1,400.00)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

3. **Correction of Alleged Deficiencies**- At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

4. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated

into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

6. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

7. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any

of its members from further participation, consideration, or resolution of these proceedings.

8. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

9. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

10. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

11. **Current Addresses**- Respondent shall keep current their mailing address and their practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

12. **Time of the Essence**- Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 6th day of December, 2022.

Institutional Representative for
Animal Health International, Inc.
CASE NO. 2021-39162

STATE OF Minnesota
COUNTY OF Wright

Sworn to (or affirmed) and subscribed before me by means of ☒ physical presence or ☐ online notarization, this 6th day of December, 2022, by Jeffrey Wigfield.

MICHELE CORINNE HALVERSON
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/26

Signature of Notary Public
Print, Type or Stamp Commissioned name of Notary Public
My Commission Expires: 01/31/2026

Personally Known_____ OR Produced Identification MN Drivers License

Type of Identification Produced MN Drivers License

APPROVED this 9th day of December, 2022.

Joseph A. Ladapo, MD, PhD
State Surgeon General

Alejandro Camacho
Assistant General Counsel

Counsel for Petitioner
Alejandro Camacho
Florida Bar No. 1018880
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 558-9839
Fax: (850) 245-4662

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2021-39162**

ANIMAL HEALTH INTERNATIONAL, INC.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Animal Health International, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to section 20.43, Florida Statutes (2021), and chapters 456 and 465, Florida Statutes (2021).

2. At all times material to this Administrative Complaint, Respondent was a permitted non-resident pharmacy within the state of Florida, having been issued license number PH29236.

3. Respondent's mailing address of record is 2915 Rocky Mountain Avenue, Suite 400, Loveland, Colorado 80538.

4. At all times material to this Administrative Complaint, Respondent was physically located at 9146 West Wolcott Industrial Parkway, Wolcott, Indiana 47995.

5. On or about February 14, 2020, in the United States District Court, Western District of Virginia, case 1:20-CR-00007, Respondent pled guilty to and/or was convicted of a misdemeanor count of Introduction of Misbranded Drugs into Interstate Commerce, a crime in violation of Title 21, United States Code, sections 331(a), 333(a)(1), and 352(f)(1).

6. The Introduction of Misbranded Drugs into Interstate Commerce count involved allegations that between on or about January 2012 and May 2015, Respondent was not properly licensed to ship veterinary prescription drugs from its Wolcott, Indiana, location to Virginia or Tennessee.

7. Section 465.016(1)(e), Florida Statutes (2021), provides that violating 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act, constitute grounds for disciplinary action.

8. Introduction of Misbranded Drugs into Interstate Commerce in violation of Title 21, United States Code, sections 331(a), 333(a)(1), and 352(f)(1), is a crime related to the practice of, and/or the ability to practice, pharmacy.

9. Section 456.072(1)(c), Florida Statutes (2021), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession constitutes grounds for disciplinary action.

10. As set forth above, Respondent was convicted of, and/or entered a plea of guilty to, a crime in the United States District Court, Western District of Virginia, which relates to the practice of, and/or the ability to practice, Respondent's profession.

11. Based on the foregoing, Respondent violated section 456.072(1)(c).

[*Remainder of Page Intentionally Left Blank.*]

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 23rd day of June 2022.

Joseph A. Ladapo, MD, PhD
State Surgeon General

By: */s/ Alejandro Camacho*
Alejandro Camacho
Assistant General Counsel
FL DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar Number 1018880
Phone: (850) 558-9839
Fax: (850) 245-4662
Alejandro.Camacho@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: *Elizabeth Eubanks*
DATE: June 23, 2022

PCP Meeting: June 23, 2022
PCP Members: Mikhael & Mesaros

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		■ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: ~~WH~~ MP01361	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Cintas Corporation No. 2

Physical Address: 250 Vista Blvd. Suite 106

City: Sparks State: NV Zip: 89434

Mailing Address (if different from physical address): ATTN: Risk & Compliance; 6800 Cintas Blvd.

City: Mason State: OH Zip: 45040

Telephone: 513-972-3969 Website: www.cintas.com

Name of Designated Representative (DR): Wayne Eble

Licensing Company Email: Regulatory@cintas.com DR Email: EbleW@cintas.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: non-prescription drugs	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Commercial End Users		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?	✓	
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				
Cintas Corporation No. 2				

Provide explanation below:

Statement in Explanation of "Yes" Re Denial of Licenses Application

On January 25, 2019 and May 6, 2019, the Utah Department of Commerce ("UDOC"), due to application non-completeness, denied Cintas Corporation No. 2's ("Cintas") applications of Pharmacy - Class E permits for facilities located in Henderson, Nevada and Mason, Ohio.

Cintas subsequently renewed the application for the Henderson, Nevada facility and the UDOC did ultimately issue the permit to Cintas on June 4, 2019 (Permit No. 11279941-1714).

In addition to issuing the permit to Cintas for the facility in Henderson, Nevada, the UDOC has also issued permits to Cintas for facilities in Salt Lake City (11107516-1714), and Sparks, Nevada (11080860-1714).

Original Signature (electronic, copies or stamps not accepted)

12/15/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				
Cintas Corporation No. 2				

Provide explanation below:

Surrendered Licenses - Cintas Corporation No. 2

MN - Wholesale Distributor Non-Resident License
- No prescription drug products

AZ - Medical Gas Supplier Resident License
- No long sells compressed medical gas

SC - Medical Gas Non-Resident License and Non-Dispensing Drug Outlet Resident License
- No prescription drug products / No controlled substances
- License Exemption granted

IL - Wholesale Drug Distributor Non-Resident License
- License Exemption granted

KY - Wholesaler Non-Resident License
- No prescription drug products
- License Exemption granted

MS - Medical Equipment Supplier Permit Non-Resident License
- License Exemption granted

PA - Distributor of Non-Prescription Drugs & Devices Non-Resident License
- No scheduled drug products
- No sales representatives operating in PA from facility

NC - Device and Medical Equipment Resident Permit
- No longer sells medical gas

Voluntary closure of facility in Mason, OH resulted in permits surrendered for these states: CT, TN, ND, TX, AR, ID, KS, LA, MN, NV, NJ, NC, OR, RI, WA, VA

Original Signature (electronic, copies or stamps not accepted)

12/15/23
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: WA

Parent Company (if any): N/A - Cintas Corporation is the Parent Company

Corporation Name: Cintas Corporation

Mailing Address: 6800 Cintas Blvd.

City: Mason State: OH Zip: 45040

Telephone: 513.972.3969 Email: Regulatory@cintas.com

Contact Person Name: Emily Wilburn

Date of SEC Registration: 08/18/1983 | SEC Registration Number: 0000723254 | Stock Exchange Symbol: CTAS

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cintas Corporation No. 2
Address: 3577 Yankee Road Suite B City: Middletown State: OH Zip: 45044

Name: Zoll Medical Corporation
Address: 269 Mill Road City: Chelmsford State: MA Zip: 01824

Name: Defibtech LLC
Address: 741 Boston Post Road Suite 201 City: Guilford State: CT Zip: 06437

Name: N/A
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NV (Cintas Corporation No. 2)
Parent Company (if any): Cintas Corporation (Publicly Traded)
Corporation/Organization Name: Cintas Corporation No. 2 (100% Corporately owned by Cintas Corporation
Mailing Address: 6800 Cintas Blvd.
City: Mason State: OH Zip: 45040
Telephone: 513-972-3969 Email: Regulatory@cintas.com
Contact Person Name: Emily Wilburn

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cintas Corporation No. 2
Facility Name

Mark Carter Jr.
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date 12/13/23

Board Use Only	Date Received: 12/14/23	Amount: $1000 - check 80020999

Brief Description Planned Business Activities Which Require This Registration

The applicant location intends to sell certain first aid products directly to commercial end users such as restaurants and offices buildings. The products sold by the applicant location will include convenience kits containing non-prescription drugs and prescription automated external defibrillators ("AEDs"). Commercial customers will obtain a prescription for the AED made out to the location where the AED will be stored, and the applicant location will deliver and install the AED at the location pursuant to the prescription.

The applicant location will not distribute any products for the purpose of resale.

Definition of Wholesale:

Cintas Corporation No. 2 meets the definition of Wholesaler per NRS 639.016.

Cintas Corporation No. 2 Officers

Todd M. Schneider – President & CEO of Cintas Corporation

J. Michael Hansen – Executive Vice President & CFO of Cintas Corporation

Jared Mattingley – Vice President & Treasurer of Cintas Corporation

Brock Denton – Sr. VP, Secretary & General Counsel of Cintas Corporation

James N. Rozakis – Executive Vice President & COO of Cintas Corporation

Mark Carter Jr. – President & COO of Cintas Corporation No. 2

Cintas Corporation No. 2 is 100% Corporately owned by Cintas Corporation

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **CINTAS CORPORATION NO. 2**, as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 04/26/2000, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/28/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202309283990637
You may verify this certificate online at http://www.nvsos.gov

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/16/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
c/o Aon Client Services
4 Overlook Point
Lincolnshire IL 60069 USA

CONTACT NAME:
PHONE (A/C, No. Ext): (866) 283-7122 FAX (A/C, No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Liberty Insurance Corporation	42404
INSURER B:	Landmark American Ins Co	33138
INSURER C:	Liberty Mutual Fire Ins Co	23035
INSURER D:	LM Insurance Corporation	33600
INSURER E:	Westchester Fire Insurance Company	10030
INSURER F:		

INSURED
Cintas Corporation and its Subsidiaries
6800 Cintas Blvd
PO Box 625737
Cincinnati OH 45262 USA

COVERAGES **CERTIFICATE NUMBER:** 570100100787 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Contractual Liability GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			TB2651004227093	07/01/2023	07/01/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$2,000,000 $1,000,000 $5,000 $1,000,000 $2,000,000 $2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY X Comp/Coll $0 Ded.			AS7-651-004227-073 AOS	07/01/2023	07/01/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
E	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $10,000			G22035277018	07/01/2023	07/01/2024	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
D D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N N N/A If yes, describe under DESCRIPTION OF OPERATIONS below			WA565D004227103 WC5651004227123	07/01/2023 07/01/2023	07/01/2024 07/01/2024	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$2,000,000 $2,000,000 $2,000,000
B	E&O - Miscellaneous Professional-Primary			LHR849266 MiscProfLiab-Claims Made	07/01/2023	07/01/2024	Each Occurrence Aggregate	$5,000,000 $5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Coverage.

CERTIFICATE HOLDER

Cintas Corporation and its Subsidiaries
PO Box 625737
Cincinnati OH 45262 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier :

Certificate No : 570100100787

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EVIDENCE OF COVERAGE

Policy Term
07-01-2023 to 07-01-2024

This Evidence of Coverage is issued as a matter of information only to authorized viewers for their internal use only and confers no rights upon any viewer of this Evidence of Coverage. This Evidence of Coverage does not amend, extend or alter the coverage described below. This Evidence of Coverage may only be copied, printed and distributed within an authorized viewer and may only be used and viewed by an authorized viewer for its internal use. Any other use, duplication or distribution of this Evidence of Coverage without the consent of Aon is prohibited. "Authorized viewer" shall mean an entity or person which is authorized by the insured named herein to access this Evidence of Coverage via www.AonLine.Aon.com. The information contained herein is as of the date referred to above. Aon shall be under no obligation to update such information.

ADDITIONAL INFORMATION

GENERAL LIABILITY

ADDITIONAL INSURED WORDING:
YOU are included as an Additional Insured on the General Liability policy where required by written contract executed prior to loss, but only for the limits agreed to in such contract or the limits of insurance of this policy, whichever is less.

WAIVER OF SUBROGATION WORDING:
Waiver of Subrogation applies in favor of YOU on the General Liability policy where required by written contract and only to the extent granted in that contract.

AUTOMOBILE LIABILITY

ADDITIONAL INSURED WORDING:
YOU are included as an Additional Insured on the Automobile Liability policy with regard to any leased vehicle where their interests may appear.

PHYSICAL DAMAGE COVERAGE:
The Named Insured assumes all Liability for Physical Damage.

WORKERS' COMPENSATION

WAIVER OF SUBROGATION:
Waiver of Subrogation Applies in favor of YOU on the Workers' Compensation policy with regard to work performed under a written contract that requires such an agreement and only to the extent granted in that contract.

The existence of more than one insured, Additional Insured or other interests shall not serve to increase the limits of liability of the policy.

The Company hereby authorizes Aon Risk Services of Ohio Inc. to issue certificates of insurance, or to display Evidence of Coverage, including any Mortgagee or Loss Payee clauses consistent with the foregoing.

The Evidence of Coverage of Insurance serves solely to list insurance policies, limits and dates of coverage. Any modifications hereto are not authorized.

VERIFICATION OF BOND IN FORCE
Form SB-3

Type of Bond: License/Permit Bond

Name of Principal: CINTAS CORPORATION NO. 2

Obligee: THE STATE OF NEVADA AND TO THE NEVADA STATE BOARD OF PHARMACY

Carrier: LIBERTY MUTUAL INSURANCE COMPANY

Bond Number: 285069851

Effective Date: June 29, 2023

Limit: $ 25,000.00

Premium: $ 100.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to June 29, 2024.

LIBERTY MUTUAL INSURANCE COMPANY

By: _____

Roger Paraison Attorney in Fact

Date: 06/26/2023

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8209007-285057**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aerie Walton, Bartlomiej Siepierski, Christina L. Sandoval, Christopher P. Troha, Corinne Chapman, Dartonya Wright, Derek J. Elston, James B. McTaggart, Jean Torres, Jennifer L. Jakaitis, Jennifer Williams, Jessica B. Dempsey, Judith A. Lucky-Eftimov, Kristin L. Hannigan, Melissa L. Fortier, Nicholas Kertesz, Rachel Fore, Roger Paraison, Samantha Chierici, Sandra M. Winsted, Susan A. Welsh, Tara A. Reimer

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of November, 2022.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 15th day of November, 2022 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of July, 2023

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Cintas Corporation No. 2 — MDEG License # (if applicable): N/A

Physical Address: 250 Vista Blvd. Suite 106

City: Sparks — State: NV — Zip: 89434

Mailing Address (if different from physical address): ATTN: Risk & Compliance; 6800 Cintas Blvd.

City: Mason — State: OH — Zip: 45040

Telephone: 513-972-3969 — Website: www.cintas.com

Licensing Company Email: Regulatory@cintas.com

Section 2: Personal Information

First: Wayne — Middle: — Last: Eble

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITI: [redacted] — Sex: ■ M ☐ F ☐ X

Mailing Addres: [redacted]

City: Reno — State: NV — Zip: 89523

Telephone: [redacted] — Email: EbleW@cintas.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

WE

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University, Stanislaus		08/01 - 08/03	
Address	**City**	**State**	**Zip**
1 University Circle	Turlock	CA	95382
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Modesto Junior College		06/98 - 08/01	
Address	**City**	**State**	**Zip**
435 College Avenue	Modesto	CA	95350
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Fred C. Beyer High School		08/94 - 06/98	
Address	**City**	**State**	**Zip**
1717 Sylvan Avenue	Modesto	CA	95355
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - Current	[redacted]	Reno	NV	89523
From - To (MM/YY – MM/YY)		City	State	Zip
04/13 - 11/16		Reno	NV	89508
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

WE

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

WE

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

WE

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/19/23
Date

WE

I, Wayne Eble, **certify that as the MDEG Administrator for**

Cintas Corporation No. 2,

that I (initial that you have read and meet the following requirements):

1. WE Have a high school diploma or its equivalent;
2. WE Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. WE Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. WE Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wayne Eble
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/14/23
Date

Board Use Only	Date Received:

WE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Cintas Corporation No. 2

Pharmacy/Wholesaler License # (if applicable): PENDING

Physical Address: 250 Vista Blvd. Suite 106

City: Sparks State: NV Zip: 89434

Mailing Address (if different from physical address): ATTN: Risk & Compliance; 6800 Cintas Blvd.

City: Mason State: OH Zip: 45040

Telephone: 513.972.3969 Website: www.cintas.com

Licensing Company Email: Regulatory@cintas.com

Section 2: Personal Information

First: Wayne Middle: Last: Eble

Alias(es, nicknames, name changes, etc.): None

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Reno State: NV Zip: 89523

Telephone: [redacted] Email: EbleW@cintas.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
California State University, Stanislaus		08/01 - 08/03	
Address	**City**	**State**	**Zip**
1 University Circle	Turlock	CA	95382
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Modesto Junior College		06/98 - 08/01	
Address	**City**	**State**	**Zip**
435 College Avenue	Modesto	CA	95350
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Fred C. Beyer High School		08/94 - 06/98	
Address	**City**	**State**	**Zip**
1717 Sylvan Avenue	Modesto	CA	95355
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/16 - Current	[redacted]	Reno	NV	89523
04/13 - 11/16		Reno	NV	89508

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Cintas Corporation			11/17 - Current	
Business Address		**City**	**State**	**Zip**
250 Vista Blvd. Suite 106		Sparks	NV	89434
Phone	**Title**		**Number of Employed Hours**	
775.352.1755	Distribution Center Manager		12,680	
Description of Duties				
Responsible for distribution center operations for both First Aid & Safety and Rental Garment business.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	✓	
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				
Cintas Corporation No. 2				

Provide explanation below:

Statement in Explanation of "Yes" Re Denial of Licenses Application

On January 25, 2019 and May 6, 2019, the Utah Department of Commerce ("UDOC"), due to application non-completeness, denied Cintas Corporation No. 2's ("Cintas") applications of Pharmacy - Class E permits for facilities located in Henderson, Nevada and Mason, Ohio.

Cintas subsequently renewed the application for the Henderson, Nevada facility and the UDOC did ultimately issue the permit to Cintas on June 4, 2019 (Permit No. 11279941-1714).

In addition to issuing the permit to Cintas for the facility in Henderson, Nevada, the UDOC has also issued permits to Cintas for facilities in Salt Lake City (11107516-1714), and Sparks, Nevada (11080860-1714).

Original Signature (electronic, copies or stamps not accepted)

12/14/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				
Cintas Corporation No. 2				

Provide explanation below:

Surrendered Licenses - Cintas Corporation No. 2

MN - Wholesale Distributor Non-Resident License
- No prescription drug products

AZ - Medical Gas Supplier Resident License
- No long sells compressed medical gas

SC - Medical Gas Non-Resident License and Non-Dispensing Drug Outlet Resident License
- No prescription drug products / No controlled substances
- License Exemption granted

IL - Wholesale Drug Distributor Non-Resident License
- License Exemption granted

KY - Wholesaler Non-Resident License
- No prescription drug products
- License Exemption granted

MS - Medical Equipment Supplier Permit Non-Resident License
- License Exemption granted

PA - Distributor of Non-Prescription Drugs & Devices Non-Resident License
- No scheduled drug products
- No sales representatives operating in PA from facility

NC - Device and Medical Equipment Resident Permit
- No longer sells medical gas

Voluntary closure of facility in Mason, OH resulted in permits surrendered for these states: CT, TN, ND, TX, AR, ID, KS, LA, MN, NV, NJ, NC, OR, RI, WA, VA

Original Signature (electronic, copies or stamps not accepted)

12/14/23
Date

I, Wayne Eble, **certify that as the designated representative for**

Cintas Corporation No. 2,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WE I am at least 21 years of age;
3. WE I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WE I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WE I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WE I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WE I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Wayne Eble

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/14/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wayne Eble

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/14/23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of WASHOE

I, Wayne Eble, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/14/23

Date

Subscribed and Sworn to before me this 14 day of DECEMBER 2023

Notary Public Signature

ZHONG WEI CHIEN
Notary Public
State of Nevada
Appt. No. 97-0064-2
My Appt. Expires Dec. 29, 2024

(Seal)

Employees of Cintas Corporation No. 2
250 Vista Blvd. Suite 106; Sparks, NV 89434

Last Name	First Name	Title
Acosta	Marcela	Quality Auditor
Blender	Frank	High Bay Operator
Duran-Moeno	Karen	HR Coordinator
Eble	Wayne	Distribution Center Manager II
Krc	Bob	LX Coordinator
Kendall	Joshua	High Bay Operator
Phan	Julia	Production Supervisor
Scanlan	Vanessa	FAS Warehouse Processor
Solano	Kevin	Coordinator – FAS
Tarrayo-Guerrero	Marilou	Customer Service Representative

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended August 31, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-11399

Cintas Corporation

(Exact name of registrant as specified in its charter)

Washington	31-1188630
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification Number)*

6800 Cintas Boulevard P.O. Box 625737 Cincinnati, Ohio	45262-5737
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant's Telephone Number, Including Area Code: (513) 459-1200

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, no par value	CTAS	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Indicate by checkmark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by checkmark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☑ No ☐

Indicate by checkmark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☑ Accelerated Filer ☐ Non-Accelerated Filer ☐
Smaller Reporting Company ☐ Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by checkmark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding September 30, 2023
Common Stock, no par value	101,854,118

CINTAS CORPORATION
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended May 31, 2023

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission file number 0-11399

Cintas Corporation
(Exact name of registrant as specified in its charter)

Washington	**31-1188630**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification Number)*
6800 Cintas Boulevard P.O. Box 625737 Cincinnati, Ohio	**45262-5737**
(Address of Principal Executive Offices)	*(Zip Code)*

Registrant's Telephone Number, Including Area Code: **(513) 459-1200**

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, no par value	CTAS	The NASDAQ Stock Market LLC (NASDAQ Global Select Market)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated Filer	☐	Non-Accelerated Filer	☐
Smaller Reporting Company	☐	Emerging Growth Company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.762(b)) by the registered public accounting firm that prepared or issued is audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b) ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the Registrant's Common Stock held by non-affiliates as of November 30, 2022, was $46,917,324,557 based on a closing sale price of $461.78 per share. As of June 30, 2023, 192,220,477 shares of the Registrant's Common Stock were issued and 101,741,564 shares were outstanding.

Documents Incorporated by Reference

Portions of the Registrant's Proxy Statement to be filed with the Commission for its 2023 Annual Meeting of Shareholders are incorporated by reference in Part III of this Form 10-K.

Cintas Corporation
Index to Annual Report on Form 10-K

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Part I

Item 1. Business

Overview

Cintas Corporation (Cintas, Company, we, us or our), a Washington corporation, helps more than one million businesses of all types and sizes, primarily in the United States (U.S.), as well as Canada and Latin America, get **READY™** to open their doors with confidence every day by providing a wide range of products and services that enhance our customers' image and help keep their facilities and employees clean, safe and looking their best. With products and services including uniforms, mats, mops, restroom supplies, first aid and safety products, fire extinguishers and testing, and safety training, Cintas helps customers get **Ready for the Workday®**. Cintas was founded in 1968 by Richard T. Farmer when he left his family's industrial laundry business in order to develop uniform programs using an exclusive new fabric. In the early 1970's, Cintas acquired the family industrial laundry business. Over the years, Cintas developed additional products and services that complemented its core uniform business and broadened the scope of products and services available to its customers.

Business Segments

Cintas' reportable operating segments are the Uniform Rental and Facility Services operating segment and the First Aid and Safety Services operating segment. The Uniform Rental and Facility Services reportable operating segment consists of the rental and servicing of uniforms and other garments, including flame resistant clothing, mats, mops and shop towels and other ancillary items. In addition to these rental items, restroom cleaning services and supplies and the sale of items from our catalogs to our customers on route are included within this reportable operating segment. The First Aid and Safety Services reportable operating segment consists of first aid and safety products and services. The remainder of Cintas' business, which consists of the Fire Protection Services operating segment and the Uniform Direct Sale operating segment, is included in All Other.

The following table sets forth Cintas' total revenue and the revenue derived from each reportable operating segment and the remaining operating segments included in the All Other category for the fiscal years ended May 31:

(In thousands)	**2023**	2022	2021
Uniform Rental and Facility Services	$ 6,897,130	$ 6,226,980	$ 5,689,632
First Aid and Safety Services	951,496	832,458	784,291
All Other	967,143	795,021	642,417
Total Revenue	$ 8,815,769	$ 7,854,459	$ 7,116,340

Additional information regarding each reportable operating segment and All Other is also included in Note 13 entitled Operating Segment Information of "Notes to Consolidated Financial Statements."

Customers

We provide our products and services to over one million businesses of all types, from small service and manufacturing companies to major corporations that employ thousands of people. This diversity in customer base results in no individual customer accounting for greater than one percent of Cintas' total revenue. As a result, the loss of one account would not have a material financial impact on Cintas.

Competition

The primary markets served by each of the Cintas operating segments are local in nature and highly fragmented. Cintas competes with national, regional and local providers, large national retailers and small local retailers as well as companies with a significant online presence and the level of competition varies at each of Cintas' local operations. In addition, businesses may decide to perform certain services in-house instead of outsourcing these services. Product, design, price, quality, service and convenience to the customer are the competitive elements in each of our operating segments.

Operations and Distribution

Within the Uniform Rental and Facility Services reportable operating segment, Cintas provides its products and services to customers via local delivery routes originating from rental processing plants and branches. Within the First Aid and Safety Services reportable operating segment and All Other, Cintas provides its products and services via its distribution network and local delivery routes or local representatives. At May 31, 2023, Cintas, in total, had approximately 11,500 local delivery routes, 461 operational facilities and 12 distribution centers.

Sourcing

Cintas is committed to sourcing responsibly. Cintas sources finished products from many outside suppliers. As mentioned on our website, www.cintas.com, each and every supplier must comply with a vendor code of conduct as a condition of doing business with Cintas. Cintas also conducts internal training to ensure that employee-partners who have direct responsibility for supply chain management are knowledgeable and aware of issues and concerns surrounding our supply chain. In addition to sourcing from third-party suppliers, Cintas operates five manufacturing facilities that provide for standard uniform needs. Cintas purchases fabric, used in the manufacturing of its products, from several suppliers. Cintas' ability to find qualified suppliers who meet its standards and to access products in a timely and efficient manner, is subject to ongoing market risks. For a discussion of the risks associated with sourcing that may materially impact Cintas, please see "Item 1A: Risk Factors - Risks Relating to Business Strategy and Operations."

Government Laws and Regulations

Cintas is subject to a wide array of laws, government regulations, including environmental regulations, and standards in each domestic and foreign jurisdiction in which it operates. In addition to Cintas' U.S. operations, which in fiscal 2023, fiscal 2022 and fiscal 2021, generated over 90% of its consolidated revenue, Cintas also operates its business through wholly-owned subsidiaries in foreign jurisdictions, primarily in Canada. Compliance with these laws, government regulations, including environmental regulations, and standards requires the dedication of time and effort of employee-partners as well as financial resources.

Compliance with environmental regulations and prioritizing our environmental sustainability efforts are important to us as a good corporate citizen. Our journey started in 1929 during the Great Depression when Doc and Amelia Farmer collected shop towels that had been disposed of by manufacturing facilities along the Ohio River. They washed, recycled and sold the clean towels back to companies. Today, the majority of our total Company revenue comes from our Uniform Rental and Facility Services reportable operating segment. Most of these items are cleaned and processed in ways that extend their lifespan and, when not in use, are re-stocked for future customers to maximize their lifespan. Our laundering processes generate far less wastewater than home laundering. Water discharged into the environment is treated at our operating facilities and in accordance with local discharge standards and permits. Our lasting commitment to the environment and our communities is evident from our processes and innovation, which are designed to ensure that our operational facilities are operating efficiently. Cintas is subject to various environmental laws and regulations, as are other companies in the uniform rental industry. The primary federal statutes that apply to our activities in the U.S. are the Clean Air Act, the Clean Water Act and the Resource Conservation and Recovery Act. We are also subject to the Superfund Amendments and Reauthorization Act of 1986, which imposes certain reporting requirements as to emissions of hazardous substances into the air, land and water. While environmental compliance is not a material component of our costs, Cintas makes capital expenditures and associated operating costs, primarily for water treatment and waste removal, on a regular basis in order to comply with environmental laws and regulations, to promote employee-partner safety and to carry out its environmental sustainability principles. Environmental spending related to water

treatment and waste removal was approximately $26.0 million in fiscal 2023, approximately $22.0 million in fiscal 2022 and approximately $19.0 million in fiscal 2021. Capital expenditures to limit or monitor hazardous substances totaled approximately $1.0 million in fiscal 2023, approximately $0.2 million in fiscal 2022 and approximately $1.0 million in fiscal 2021.

In addition, health and safety regulations (including laws or regulations promulgated in response to the novel strain of coronavirus (COVID-19) pandemic) have necessitated, and may continue to necessitate, increased operating costs or capital investments to promote a safe working environment. Cintas is also required to comply with increasingly complex and changing laws and regulations enacted to protect business and personal data in the U.S. and other jurisdictions regarding privacy, data protection and data security, including those related to the collection, storage, use, transmission and protection of personal information and other consumer, customer, vendor or employee data. With respect to the laws and regulations noted above, as well as other applicable laws and regulations, Cintas' compliance programs may under certain circumstances involve material investments in the form of additional processes, training, personnel, information technology and capital. In fiscal 2023, compliance with the applicable laws, government regulations, including environmental regulations, and standards did not have a material effect on Cintas' capital expenditures or consolidated results of operations. For a discussion of the risks associated with government regulations that may materially impact Cintas, please see "Item 1A: Risk Factors—Legal and Regulatory Risks."

Communication

Cintas uses its corporate website, www.cintas.com, as a channel for routine distribution of important information, including news releases, analyst presentations and financial information. Cintas files with, or furnishes to, the Securities and Exchange Commission (SEC) Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as well as proxy statements and annual reports to shareholders, and, from time to time, other documents. The reports and other documents filed with or furnished to the SEC are available to investors on or through our corporate website free of charge as soon as reasonably practicable after we electronically file them with or furnish them to the SEC. The SEC maintains an internet site located at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers, such as Cintas, that file electronically with the SEC. Cintas' SEC filings can be found on the Investor Relations page of its website at www.cintas.com/investors/financial-reports and its Code of Conduct and Business Ethics can be found under the Impact page of its website at www.cintas.com/company/esg. These documents are available in print to any shareholder who requests a copy by writing or calling Cintas as set forth on the Investor Information page under the FAQs. The content on any website referred to in this Annual Report on Form 10-K is not incorporated herein by reference unless expressly noted.

Environmental, Social and Governance

In fiscal 2023, Cintas published its third annual environmental, social and governance (ESG) report and reported on Cintas' continued strategy of a Shared Drive for Better. The report included information on Cintas' efforts in areas of climate and energy initiatives, water interactions, materials and waste, sustainable supply chain, diversity, equity and inclusion efforts, employee-partner development, safety and health strategy, human rights and labor rights positions and governance, ethics and integrity foundations. Cintas' most recent ESG report can be found on our website at www.cintas.com/company/esg.

Human Capital

Cintas' key human capital management objectives are to attract, retain and develop talent to deliver on the Company's strategy. To support these objectives, Cintas' human resources programs are designed to: keep people safe and healthy; enhance the Company's culture through efforts aimed at making the workplace more inclusive; acquire and retain diverse talent; reward and support employee-partners through competitive pay and benefit programs; develop talent to prepare them for critical roles and leadership positions; and facilitate internal talent mobility to create a high-performing workforce. The principles and values our employee-partners share are the driving force behind all our accomplishments. At May 31, 2023, Cintas employed approximately 44,500 employee-partners in our global workforce, of which approximately 1,000 were represented by labor unions.

Our primary areas of focus in managing our human capital include the following:

Corporate Culture

We believe that our culture at Cintas is just as essential as our products and services. Our culture impacts the quality of the employee-partners we hire, the way we communicate and interact with our customers and each other and our performance standards. Our culture is the cornerstone representing our values, our behaviors, our way of working and how we approach our business, which is strong relationships and a dedication to taking care of one another and our customers. We operate according to the Cintas Code of Conduct, available on our website www.cintas.com, which mandates full compliance with applicable laws and regulations and helps to preserve the integrity of our Company.

Health and Safety

We aspire to achieve zero workplace injuries and collisions and provide a safe, open, healthy and accountable work environment for our employee-partners. To align with internationally recognized standards, we have implemented an occupational health and safety management system in accordance with the Occupational Safety and Health Administration (OSHA) that is modeled after the International Organization for Standardization (ISO) 45001 and OSHA Voluntary Protection Program (VPP). Employee-partners, contractors, vendors and visitors are all covered by the system, which focuses on hazard prevention, training, management commitment and worker involvement. We are also committed to continuously improving performance through our Health and Safety Improvement Committees in every operation, while corporate health and safety employee-partners conduct annual reviews of our operations. Additionally, every year our employee-partners receive online, on-the-job and classroom training on over 50 health and safety topics, and all maintenance staff must complete our award-winning Maintenance Safety Certification process. Every Cintas driver completes monthly driver safety training courses and/or on-the-road skills evaluations. All production-related managers attend OSHA's 10-hour Safety Improvement course, and each member of our Senior Management team takes the Management and Leadership Skills for Environmental Health and Safety Professionals Course, part of the Harvard T.H Chan School of Public Health safety and health curriculum. In addition, we provide several channels for all employee-partners to speak up, ask for guidance and report concerns related to ethics or safety violations, and we address those concerns and take appropriate actions to uphold our Cintas values and health and safety culture. Through these efforts, Cintas has reduced our recordable injury rate by over 75% since 2008, has been awarded 124 OSHA Star sites in the VPP, which is more than triple any other company in the U.S. and has received numerous safety, health and ergonomics awards from national and international groups.

Employee-Partner Wellness

We are committed to the physical and mental health and wellness of our employee-partners. We provide our employee-partners and their families with access to a variety of health and wellness programs, including our long-running Live Well program that supports employee-partners on their health and wellness journeys. We provide free annual biometric screening and health assessments at work or offsite, annual free flu shot clinics, a tobacco cessation program, weight management programs and an employee-partner assistance program, which offers advice on mental health, legal and financial issues.

Diversity, Equity & Inclusion

Cintas supports diversity, equity and inclusion by fostering a respectful, creative and productive environment where all employee-partners can reach their full potential without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability or protected veteran status. We actively recruit, retain, develop and advance a diverse and talented workforce. We have six Employee-Partner Business Resource Groups, focused on Women, African Americans, Hispanic and Latin Americans, Asian American/Pacific Islanders, LGBTQ+ and Military and Veteran employee-partners. These groups provide platforms for our employee-partners to showcase skills, experiences and perspectives. The Employee-Partner Business Resource Groups also help foster inclusion among all employee-partners to build awareness, recruit and retain a diverse workforce and support the overall success of Cintas. We also have a diverse Management Trainee program that helps Cintas find and develop the best talent for our leadership pipeline, and we monitor representation across management positions. Cintas' diversity, equity and inclusion efforts are led by our Senior Vice President of Human Resources and Chief Diversity Officer. This position reports to our Chief Executive Officer and works to help achieve our goals and obtain a diverse and talented workforce, which is critical to our success.

Compensation Programs and Employee Benefits

Our compensation and benefits programs provide a total rewards package designed to attract, retain and motivate our employee-partners. In addition to competitive base salaries, the total rewards package (which may vary by position and country) includes, among other items, bonuses, long-term incentives, retirement savings plans, medical insurance, prescription drug benefits, dental insurance, vision insurance, accident and critical illness insurance, life and disability insurance, health savings accounts, flexible spending accounts and an employee-partner assistance program.

Talent Development

Cintas is committed to the continued development of its employee-partners. We provide numerous training opportunities for our employee-partners, with a focus on continuous learning and development and methodologies to manage performance, provide feedback and develop talent. We offer a wide array of training solutions (classroom, hands-on and e-learning) for our employee-partners. Our talent development programs strive to provide employee-partners resources to achieve career goals and build management and leadership skills. We offer mentoring programs, a management trainee program and executive leadership programs to support the professional growth of our employee-partners and ensure we have the right succession plans in place.

Item 1A. Risk Factors

The statements in this section describe the most significant risks that could materially and adversely affect our business, consolidated financial condition and consolidated results of operation and the trading price of our debt or equity securities. Although the risks are organized by headings, and each risk is discussed separately, many are interrelated. Readers should not interpret the disclosure of any risk factor to imply that the risk has not already materialized.

In addition, this section sets forth statements which constitute our cautionary statements under the Private Securities Litigation Reform Act of 1995.

This Annual Report on Form 10-K contains forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a safe harbor from civil litigation for forward-looking statements. Forward-looking statements may be identified by words such as "estimates," "anticipates," "predicts," "projects," "plans," "expects," "intends," "target," "forecast," "believes," "seeks," "could," "should," "may" and "will" or the negative versions thereof and similar words, terms and expressions and by the context in which they are used. Such statements are based upon current expectations of Cintas and speak only as of the date made. You should not place undue reliance on any forward-looking statement. We cannot guarantee that any forward-looking statement will be realized. These statements are subject to various risks, uncertainties, potentially inaccurate assumptions and other factors that could cause actual results to differ from those set forth in or implied by this Annual Report. Factors that might cause such a difference include, but are not limited to, the possibility of greater than anticipated operating costs including energy and fuel costs; lower sales volumes; loss of customers due to outsourcing trends; the performance and costs of integration of acquisitions; inflationary pressures and fluctuations in costs of materials and labor, including increased medical costs; interest rate volatility; costs and possible effects of union organizing activities; failure to comply with government regulations concerning employment discrimination, employee pay and benefits and employee health and safety; the effect on operations of exchange rate fluctuations, tariffs and other political, economic and regulatory risks; uncertainties regarding any existing or newly-discovered expenses and liabilities related to environmental compliance and remediation; our ability to meet our goals relating to ESG opportunities, improvements and efficiencies; the cost, results and ongoing assessment of internal controls for financial reporting; the effect of new accounting pronouncements; disruptions caused by the inaccessibility of computer systems data, including cybersecurity risks; the initiation or outcome of litigation, investigations or other proceedings; higher assumed sourcing or distribution costs of products; the disruption of operations from catastrophic or extraordinary events including global health pandemics such as the COVID-19 coronavirus; the amount and timing of repurchases of our common stock, if any; changes in federal and state tax and labor laws; and the reactions of competitors in terms of price and service. Cintas undertakes no obligation to publicly release any revisions to any forward-looking statements or to otherwise update any forward-looking statements whether as a result of new information or to reflect events, circumstances or any other unanticipated developments arising after the date on which such statements are made, except otherwise as required by law. The risks and uncertainties described herein are not the only ones we may face. Additional risks and uncertainties presently not known to us or that we currently believe to be immaterial may also harm our business. Forward-looking and other statements in this Annual Report on Form 10-K regarding our greenhouse gas (GHG) reduction plans and other ESG goals are not an indication that these statements are necessarily material to investors or required to be disclosed in our filings with the SEC. In addition, historical, current and forward-looking GHG-related and/or ESG-related statements may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future.

Risks Relating to Business Strategy and Operations

Negative global economic factors may adversely affect our financial performance.

Negative economic conditions, in North America and our other markets, may adversely affect our financial performance. Higher levels of unemployment, inflation, recessionary conditions, geopolitical developments, tax rates and other changes in tax laws and other economic factors could adversely affect the demand for Cintas' products and services. Increases in labor costs, including the cost to provide employee-partner related healthcare benefits, minimum wages, labor shortages or shortages of skilled labor, regulations regarding the classification of employees and/or their eligibility for overtime wages, higher material costs for items such as fabrics and textiles,

the inability to obtain insurance coverage at cost-effective rates, higher interest rates, inflation, global health pandemics such as the COVID-19 pandemic, higher tax rates and other changes in tax laws and other economic factors could increase our cost of labor, uniforms and facility services, cost of other services and selling and administrative expenses. As a result, these factors could adversely affect our sales and consolidated results of operations.

Increased competition could adversely affect our financial performance.

We operate in highly competitive industries and compete with national, regional and local providers. Product, design, price, quality, service and convenience to the customer are the competitive elements in these industries. If existing or future competitors seek to gain or retain market share by reducing prices, Cintas may be required to lower prices, which would hurt its results of operations. Cintas competitors also generally compete with Cintas for acquisition candidates, which can increase the price for acquisitions and reduce the number of available acquisition candidates. In addition, our customers and prospects may decide to perform certain services in-house instead of outsourcing these services to us. These competitive pressures could adversely affect our sales and consolidated results of operations.

An inability to open new, cost effective operating facilities may adversely affect our expansion efforts.

We plan to expand our presence in existing markets and enter new markets. The opening of new operating facilities is necessary to gain the capacity required for this expansion. Our ability to open new operating facilities depends on our ability to identify attractive locations, negotiate leases or real estate purchase agreements on acceptable terms, identify and obtain adequate utility and water sources and comply with environmental regulations, zoning laws and other similar factors. Any inability to effectively identify and manage these items may adversely affect our expansion efforts, and consequently, adversely affect our financial performance.

Risks associated with our acquisition practice could adversely affect our consolidated results of operations.

Historically, a portion of our growth has come from acquisitions. We continue to evaluate opportunities for acquiring businesses that may supplement our internal growth. However, there can be no assurance that we will be able to locate and purchase suitable acquisitions. In addition, the success of any acquisition, including the ability to realize anticipated cost synergies, depends in part on our ability to integrate the acquired company. The process of integrating acquired businesses may involve unforeseen difficulties and may require a disproportionate amount of our management's attention and our financial and other resources. If management is not able to effectively manage the integration process, or if any significant business activities are interrupted as a result of the integration process, we may not be able to realize anticipated cost synergies resulting from acquisitions and our business could suffer. Although we conduct due diligence investigations prior to each acquisition, there can be no assurance that we will discover or adequately protect against all material liabilities of an acquired business for which we may be responsible as a successor owner or operator. The failure to identify suitable acquisitions and successfully integrate these acquired businesses, or to discover liabilities associated with such businesses in the diligence process, could adversely affect our consolidated results of operations.

Risks associated with the suppliers from whom our products are sourced could adversely affect our consolidated results of operations.

The products we sell are sourced from a wide variety of domestic and international suppliers. Global sourcing of many of the products we sell is an important factor in our financial performance. We require all our suppliers to comply with applicable laws, including labor and environmental laws, and otherwise be certified as meeting our required supplier standards of conduct. Our ability to find qualified suppliers who meet our standards, and to access products in a timely and efficient manner, is a significant challenge, especially with respect to suppliers located and goods sourced outside the U.S. Political and economic stability in the countries in which foreign suppliers are located, the financial stability of suppliers, suppliers' failure to meet our supplier standards, labor problems experienced by our suppliers, the availability of raw materials to suppliers, currency exchange rates, transport availability and cost, inflation and other factors relating to the suppliers and the countries in which they are located are beyond our control. In addition, U.S. and foreign trade policies, tariffs and other impositions on imported goods, trade sanctions imposed on certain countries, the limitation on the importation of certain types

of goods or of goods containing certain materials from other countries and other factors relating to foreign trade are beyond our control. Taxes and other factors, including the potential negative impact of global health pandemics such as COVID-19, affecting our workforce and our access to products could adversely affect our consolidated results of operations.

We rely extensively on computer systems, including third-party systems, to process transactions, maintain information and manage our businesses. Disruptions in the availability of computer systems due to implementation of a new system or otherwise, or privacy breaches involving computer systems, could impact our ability to service our customers and adversely affect our sales, consolidated results of operations and reputation and expose us to litigation risk.

Our businesses rely on various computer systems, including third-party systems, to provide customer information, process customer transactions and provide other general information necessary to manage our businesses. We have an active disaster recovery plan in place that is frequently reviewed and tested. However, our computer systems are subject to damage or interruption due to system conversions, power outages, computer or telecommunication failures, catastrophic events such as fires, tornadoes and hurricanes and usage errors by our employees. Although we believe that we have adopted appropriate measures to mitigate potential risks to our technology and our operations from these information technology-related and other potential disruptions, given the unpredictability of the timing, nature and scope of such disruptions, we could potentially be subject to production downtimes, operational delays and interruptions in our ability to provide products and services to our customers. Any disruption caused by the unavailability of our computer systems could adversely affect our sales, could require us to make a significant investment to fix or replace them and, therefore, could adversely affect our consolidated results of operations. In addition, cyber-security attacks are evolving and have become increasingly more sophisticated. Cyber-security attacks may include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, unauthorized release of confidential or otherwise protected information and corruption of data. We have experienced cybersecurity incidents in the past, but none of these incidents, individually or in the aggregate, have had a material adverse effect on our business or results of operations. If the network of security controls, policy enforcement mechanisms and monitoring systems to address these threats to our technology fails, or we are unable to successfully address security incidents, production downtimes, operational delays and interruptions in our ability to provide products and services to our customers, the compromising of confidential or otherwise protected Company, customer, or employee information, destruction or corruption of data, security breaches, or other manipulation or improper use of our systems and networks could result in financial losses from remedial actions, loss of business or potential liability and damage to our reputation.

We also rely on software applications, enterprise cloud storage systems and cloud computing services provided by third-party vendors for certain information technology services, including our SAP enterprise system, payroll data, risk management data and lease data. If these third-party vendors, as well as our suppliers and other vendors, experience service interruptions or damage, security breaches, cyber-attacks, computer viruses, ransomware or other similar events or intrusions, our business and our consolidated results of operations may be adversely affected.

Failure to achieve and maintain effective internal controls could adversely affect our business and stock price.

Effective internal controls are necessary for us to provide reliable financial reports. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to the consolidated financial statement preparation and presentation. While we continue to evaluate our internal controls, we cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. If we fail to maintain the adequacy of our internal controls or if we or our independent registered public accounting firm were to discover material weaknesses in our internal controls, as such standards are modified, supplemented or amended, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. Failure to achieve and maintain an effective internal control environment could cause us to be unable to produce reliable financial reports or prevent fraud. This may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price.

We may experience difficulties in attracting and retaining competent personnel in key positions. Failure to preserve positive labor relationships with our employees could adversely affect our consolidated results of operations.

We believe that a key component of our success is our corporate culture, which has been fostered by management throughout our corporate organization. Our corporate culture, along with our entire operation, depends on our ability to attract, develop and retain key employees. Competitive pressures and labor shortages within and outside our industry may make it more difficult and expensive for us to attract and retain key employees which could adversely affect our businesses.

We believe we have positive labor relationships with our employees. However, factors such as difficulty to attract key employees, reduced employee engagement, third-party organizational efforts and increased employee turnover could adversely affect our labor relationships with our employees. A failure to preserve positive labor relationships with our employees and could adversely affect our consolidated financial condition and consolidated results of operations.

Unexpected events could negatively impact our business and adversely affect our consolidated results of operations.

Unexpected events, including fires or explosions at facilities, severe weather conditions and natural disasters such as hurricanes and tornadoes (including those caused by climate change), war or terrorist activities, unplanned outages, global health pandemics such as COVID-19, supply disruptions, failure of equipment or systems or changes in laws and/or regulations impacting our businesses, could adversely affect our consolidated results of operations. These events could result in customer disruption, physical damage to one or more key operating facilities, the temporary closure of one or more key operating facilities or the temporary disruption of information systems. In addition, negative publicity, whether warranted or not, impacting brand image perception could adversely affect our consolidated results of operations.

Financial Risks

Our indebtedness may limit cash flow available to invest in the ongoing needs of our business.

Our outstanding indebtedness along with adverse interest rate fluctuations may have negative consequences on our business, such as requiring us to dedicate a substantial portion of our cash flow from operations to the payment of debt service, reducing the availability of our cash flow to fund working capital, capital expenditures, acquisitions, dividend increases, stock buybacks and other general corporate purposes, as well as increase our vulnerability to adverse economic or industry conditions. In addition, it may limit our ability to obtain additional financing in the future to enable us to react to changes in our business or industry or place us at a competitive disadvantage compared to businesses in our industry that have less debt.

Changes in the fuel and energy industry could adversely affect our consolidated financial condition and consolidated results of operations.

The price of fuel and energy needed to run our vehicles and equipment is unpredictable and fluctuates based on events outside our control, including geopolitical developments, supply and demand for fuel and other energy related products, actions by energy producers, war and unrest in oil producing countries, regional production patterns, limits on refining capacities, natural disasters, environmental concerns including the impact of legislative and regulatory efforts to limit GHG emissions and global health pandemics such as COVID-19. Increases in fuel and energy costs could adversely affect our consolidated financial condition and consolidated results of operations.

Fluctuations in foreign currency exchange could adversely affect our consolidated financial condition and consolidated results of operations.

We earn revenue, pay expenses, own assets and incur liabilities in countries using currencies other than the U.S. dollar, primarily the Canadian dollar. In fiscal years 2023, 2022 and 2021, revenue denominated in currencies other than the U.S. dollar represented less than 10% of our consolidated revenue. Because our consolidated financial statements are presented in U.S. dollars, we must translate revenue and expenses, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, fluctuations

In the value of the U.S. dollar against other major currencies, particularly in the event of significant increases in foreign currency revenue, will impact our revenue and operating income and the value of balance sheet items denominated in foreign currencies. This impact could adversely affect our consolidated financial condition and consolidated results of operations.

We may recognize impairment charges, which could adversely affect our consolidated financial condition and consolidated results of operations.

We assess our goodwill and other intangible assets and our long-lived assets for impairment when required by U.S. Generally Accepted Accounting Principles (U.S. GAAP). These accounting principles require that we record an impairment charge if circumstances indicate that the asset carrying values exceed their estimated fair values. The estimated fair value of these assets is impacted by, but not limited to, macroeconomic, industry and market conditions in the locations in which we operate. Deterioration in these general economic conditions may result in: declining revenue, which can lead to excess capacity and declining operating cash flow; reductions in management's estimates for future revenue and operating cash flow growth; increases in borrowing rates and other deterioration in factors that impact our weighted average cost of capital; and deteriorating real estate values. If our assessment of goodwill, other intangible assets or long-lived assets indicates an impairment of the carrying value for which we recognize an impairment charge, this may adversely affect our consolidated financial condition and consolidated results of operations.

The effects of credit market volatility and changes in our credit ratings could adversely affect our liquidity and consolidated results of operations.

Our operating cash flows, combined with access to the credit markets, provide us with significant discretionary funding capacity. However, deterioration in the global credit markets may limit our ability to access credit markets, which could adversely affect our liquidity and/or increase our cost of borrowing. In addition, credit market deterioration and its actual or perceived effects on our results of operations and financial condition, along with deterioration in general economic conditions, may increase the likelihood that the major independent credit agencies will downgrade our credit ratings, which could increase our cost of borrowing. Increases in our cost of borrowing could adversely affect our consolidated results of operations.

Legal and Regulatory Risks

Failure to comply with federal and state regulations to which we are subject could result in penalties or costs that could adversely affect our consolidated results of operations.

Our business is subject to complex and stringent state and federal regulations, including employment laws and regulations, minimum wage requirements, overtime requirements, working condition requirements, citizenship requirements, transportation and other laws and regulations. In particular, we are subject to the regulations promulgated by the U.S. Department of Transportation (USDOT) and under the Occupational Safety and Health Act of 1970, as amended (OSHA Act). We have incurred, and will continue to incur, capital and operating expenditures and other costs in the ordinary course of our business in complying with the USDOT regulations, the OSHA Act and other laws and regulations to which we are subject. Changes in laws, regulations and the related interpretations, including any laws or regulations that may be enacted by the current U.S. presidential administration and Congress, may alter the landscape in which we do business and may affect our costs of doing business. The impact of new laws and regulations cannot be predicted. Compliance with new laws and regulations may increase our operating costs or require significant capital expenditures. Any failure to comply with applicable laws or regulations could result in substantial fines by government authorities, payment of damages to private litigants, or possible revocation of our authority to conduct our operations, which could adversely affect our ability to service customers and our consolidated results of operations.

We are subject to legal proceedings that may adversely affect our consolidated financial condition and consolidated results of operations.

We are subject to various litigation claims and legal proceeding arising from the ordinary course of our business, including personal injury, customer contract, environmental and employment claims. Certain of these lawsuits or potential future lawsuits, if decided adversely to us or settled by us, may result in liability and expense material to our consolidated financial condition and consolidated results of operations.

Compliance with environmental laws and regulations could result in significant costs that adversely affect our consolidated results of operations.

Our operating facilities are subject to environmental laws and regulations relating to the protection of the environment and health and safety matters, including those governing discharges of pollutants to the air and water, the management and disposal of hazardous substances and wastes and the clean-up of contaminated sites. The operation of our businesses entails risks under environmental laws and regulations. We could incur significant costs, including clean-up costs, fines and sanctions and claims by third parties for property damage and personal injury, as a result of violations of or liabilities under these laws and regulations. We are currently involved in a limited number of remedial investigations and actions at various locations. While based on information currently known to us, we believe that we maintain adequate reserves with respect to these matters, our liability could exceed forecasted amounts, and the imposition of additional clean-up obligations or the discovery of additional contamination at these or other sites could result in significant additional costs which could adversely affect our results of operations. In addition, potentially significant expenditures could be required to comply with environmental laws and regulations, including requirements that may be adopted or imposed in the future.

Under applicable environmental laws, an owner or operator of real estate may be required to pay the costs of removing or remediating hazardous materials located on or emanating from property, whether or not the owner or operator knew of or was responsible for the presence of such hazardous materials. While we regularly engage in environmental due diligence in connection with acquisitions, we can give no assurance that locations that have been acquired or leased have been operated in compliance with environmental laws and regulations during prior periods or that future uses or conditions will not make us liable under these laws or expose us to third-party actions, including tort suits.

Increased global focus on climate change may result in the imposition of new or additional regulations or requirements applicable to, and increased financial risks for, our business and industry. A number of government authorities and agencies have introduced or are contemplating regulatory changes to address climate change, including the regulation of GHG emissions. The outcome of new legislation or regulation in the U.S. and other jurisdictions in which we operate may result in new or additional requirements, including to fund energy efficiency activities or renewable energy use, and fees or restrictions on certain activities or materials. Compliance with these climate change initiatives may also result in additional costs to us, including, among other things, increased production costs, additional taxes, additional investments in renewable energy use and other initiatives, reduced emission allowances or additional restrictions on production or operations. We may not be able to timely recover the cost of compliance with such new or more stringent laws and regulations, which could adversely affect our consolidated results of operations.

Our ability to achieve our environmental, social and governance goals are subject to risks, many of which are outside of our control, and our reputation and brands could be harmed if we fail to meet such goals.

Companies across all industries are facing increasing scrutiny from stakeholders related to ESG matters, including practices and disclosures related to environmental stewardship; social responsibility; diversity, equity and inclusion; and workplace rights. Our ability to achieve our ESG goals, including our goal to achieve Net Zero GHG emissions by 2050, and to accurately and transparently report our progress presents numerous operational, financial, legal and other risks, and may be dependent on the actions of suppliers and other third parties, significant technological advancements with respect to the development and availability of reliable, affordable and sustainable alternative solutions, all of which are outside of our control. If we are unable to meet our ESG goals or evolving stakeholder expectations and industry standards, or if we are perceived to have not responded appropriately to the growing concern for ESG issues, our reputation could be negatively impacted. In addition, in recent years, investor advocacy groups and certain institutional investors have placed increasing importance on ESG matters. If, as a result of their assessment of our ESG practices, certain investors are unsatisfied with our actions or progress, they may reconsider their investment in our Company.

As the nature, scope and complexity of ESG reporting, diligence and disclosure requirements expand, including the SEC's recently proposed disclosure requirements regarding, among other matters, GHG emissions, we may have to undertake additional costs to control, assess and report on ESG metrics. Any failure or perceived failure, whether or not valid, to pursue or fulfill our ESG goals, targets and objectives or to satisfy various ESG reporting standards within the timelines we announce, or at all, could increase the risk of litigation.

Increases in income tax rates, changes in income tax laws or unfavorable resolution of tax matters could adversely impact our consolidated results of operations.

Changes in tax laws or regulations in the jurisdictions in which we do business, or other tax law implementation or interpretations, including the Inflation Reduction Act (IRA), which includes a corporate alternative minimum tax on certain large corporations, incentives to address climate change mitigation and other non-income tax provisions, including an excise tax on the repurchase of corporate stock could increase our effective tax rate, restrict our ability to repatriate undistributed offshore earnings, or impose new restrictions, costs or prohibitions on our current practices and reduce our net income and adversely affect our cash flows.

We are also subject to tax audits, including with respect to transfer pricing, in the U.S. and other jurisdictions and our tax positions may be challenged by tax authorities. Although we believe that our current tax provisions are reasonable and appropriate, there can be no assurance that these items will be settled for the amounts accrued, that additional tax exposures will not be identified in the future or that additional tax reserves will not be necessary for any such exposures. Any increase in the amount of taxation incurred as a result of challenges to our tax filing positions could result in a material adverse effect on our business, consolidated results of operations and consolidated financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Cintas occupies 473 facilities located in 333 cities. Cintas leases 245 of these facilities for various terms ranging from monthly to the year 2034. Cintas expects that it will be able to renew or replace its leases on satisfactory terms. Of the five manufacturing facilities noted below, all but one are owned by Cintas. The principal executive office in Cincinnati, Ohio, provides centrally located administrative functions including accounting, finance, marketing and computer system development and support. Cintas operates rental processing plants that house administrative, sales and service personnel and the necessary equipment involved in the cleaning of uniforms and bulk items, such as entrance mats and shop towels. Branch operations provide administrative, sales and service functions. Cintas operates 12 distribution centers and five manufacturing facilities. Cintas also operates first aid and safety and fire protection facilities and direct sales offices. Cintas considers the facilities it operates to be adequate for their intended use. Cintas owns or leases approximately 20,900 vehicles which are used for the route-based services and by the sales and management employee-partners.

The following chart provides additional information concerning Cintas' facilities:

Type of Facility	# of Facilities
Rental Processing Plants	205
Rental Branches	135
First Aid and Safety Facilities	63
All Other Facilities	53
Distribution Centers [1]	12
Manufacturing Facilities	5
Total	473

[1] Includes the principal executive office, which is attached to the distribution center in Cincinnati, Ohio.

Certain facilities are utilized by multiple operating segments. These facilities are only presented once, in their primary operating segment, herein. Rental processing plants, rental branches, distribution centers and manufacturing facilities are used in Cintas' Uniform Rental and Facility Services reportable operating segment. First aid and safety facilities, rental processing plants and distribution centers are used in the First Aid and Safety Services reportable operating segment. Rental processing plants, rental branches, first aid and safety facilities, fire protection facilities, direct sales offices, distribution centers and manufacturing facilities are all utilized by the operating segments included in All Other.

Item 3. Legal Proceedings

We discuss material legal proceedings (other than ordinary routine litigation incidental to our business) pending against us in "Item 8. Financial Statements and Supplementary Data," in Note 14 entitled Litigation and Other Contingencies of "Notes to Consolidated Financial Statements." We refer you to and incorporate by reference into this Item 3 that discussion for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought.

Item 4. Mine Safety Disclosures

Not applicable.

4V

WH03580

Maria Herrera

From: Silker, Chad <chad.silker@zoetis.com>
Sent: Thursday, January 11, 2024 10:01 AM
To: Mark I. Sedar
Cc: Maria Herrera; Zoetis Supply Chain & Logistics
Subject: Zoetis US LLC Request for Temporary Wholesale License

Importance: High

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

We submitted an Out of State Wholesaler application in early December for our Zoetis logistics facility at 1100 NW Main St, Unit D in Lee's Summit MO 64086.

I would like to request a temporary Nevada Wholesale license for this facility until our application can be reviewed/approved at your March board meeting.

We are standing up this new facility in Lee's Summit MO as the supply hub for Zoetis product, and also have a supply spoke in Reno NV (NV license WH0990) that we would like to start supplying out of the new facility. It will impact operations considerably if we cannot ship to our Reno NV facility until March.

I believe the application is complete and we have satisfied the requested deficiencies. If there is anything else you need please let us know.

Thanks and Stay Safe!

Chad Silker; Network Support Manager
Zoetis | Supply Chain & Logistics - United States | One Pfizer Way Lee's Summit MO 64081
Office: 816-246-2266 | Mobile: 816-332-0760 | chad.silker@zoetis.com
Visit Us: www.zoetisUS.com

HOME SAFE, EVERY DAY

TRMP
APPROVED
SDW
1/20/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Zoetis US LLC

Physical Address: 1100 NW Main Str., Unit d

City: Lee's Summit State: MO Zip: 64086

Mailing Address (if different from physical address): One Pfizer Way

City: lee's Summit State: MO Zip: 64081

Telephone: 816-246-2266 Website: Zoetis.com

Name of Designated Representative (DR): Ed Capehart

Licensing Company Email: zoetisscl@zoetis.com DR Email: ed.capehart@zoetis.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others:	☐ Warehouse
☐ Veterinarians	Veterinay non-controlled	☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis Inc
Address: 10 Sylvan Way City: Parsippany State: NJ Zip: 07054
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: NJ
Parent Company (if any):
Corporation Name: Zoetis US LLC
Mailing Address: 10 Sylvan Way
City: Parsippany State: NJ Zip: 07054
Telephone: 816-246-2266 Email: ZoetisSCL@zoetis.com
Contact Person Name: Chad Silker

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration #1910179 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Zoetis US LLC

Facility Name

Chad Silker

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

05 Dec 23

Date

Board Use Only	Date Received: 12/7/23	Amount: $1000 - CC ✓

10 Sylvan Way
Parsippany, NJ 07054

zoetis

Zoetis US LLC Corporate Officers

Name	Position
Ed DuBeau	President
Redouan Nhili	Vice President
Chad M Silker	Power of Attorney

Top 10 Owners of Zoetis Inc

Stockholder	Stake	Shares owned	Total value ($)	Shares bought / sold	Total change
The Vanguard Group, Inc.	7.42%	35,255,632	5,438,181,236	-507,017	-1.42%
BlackRock Fund Advisors	4.93%	23,429,257	3,613,962,892	+339,224	+1.47%
SSgA Funds Management, Inc.	4.23%	20,088,655	3,098,675,034	-371,551	-1.82%
State Farm Investment Management ...	3.82%	18,133,315	2,797,063,839	0	0.00%
AllianceBernstein LP	3.50%	16,645,263	2,567,531,818	+1,386,823	+9.09%
Fidelity Management & Research Co...	2.78%	13,191,940	2,034,856,745	+2,870,119	+27.81%
Polen Capital Management LLC	2.32%	11,024,646	1,700,551,646	+244,464	+2.27%
T. Rowe Price Associates, Inc. (I...	1.92%	9,120,294	1,406,805,350	+875,491	+10.62%
Capital Research & Management Co....	1.88%	8,948,806	1,380,353,326	-517,516	-5.47%
ClearBridge Investments LLC	1.86%	8,845,759	1,364,458,326	-536,056	-5.71%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ZOETIS US LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-EIGHTH DAY OF JULY, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2892324 8300

SR# 20233111021

Authentication: 203849093

Date: 07-28-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Missouri

Division of Professional Registration
Licensed Drug Distributor
Out of State Wholesale

VALID THROUGH OCTOBER 31, 2025
ORIGINAL CERTIFICATE/LICENSE NO. 2023039647
ZOETIS US LLC
ZOETIS US LLC
BRANDON SHUMAKER, MIC
1100 NW MAIN ST, UNIT D
LEE'S SUMMIT MO 64086
USA

ZOETIS US LLC
ZOETIS US LLC
BRANDON SHUMAKER, MIC
1100 NW MAIN ST, UNIT D
LEE'S SUMMIT MO 64086
USA

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy
Licensed Drug Distributor

Out of State Wholesale

VALID THROUGH OCTOBER 31, 2025
ORIGINAL CERTIFICATE/LICENSE NO. 2023039647
Brandon Shumaker

ZOETIS US LLC
ZOETIS US LLC
BRANDON SHUMAKER, MIC
1100 NW MAIN ST, UNIT D
LEE'S SUMMIT MO 64086
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

Zoetis Structure Chart
As of July 2023

Note: All entities owned 100% unless indicated.

Lee's Summit Logistics Center
Colleague
Binkley, Grant
Boak, Andy
Brown, Taylor
Burr, John
Canady, Ron
Capehart, Ed - Operations Coordinator
Clark, Ronald
Diggs, Taylor
Fairman, Darryl
Fry, James
Fry, Jim
Gibson, Ben
Hayes, Mitzie
Hogue, Charles
Hollandsworth, John
Hudson, Kyle
Johnson, Kenny
Kafer, Anthony
Kirubakaran, Sanj
Lansangan, Skyler
Lehner, Richard
Little, Gidget
Loveall, Brian
Lungay, James
Miller, Mark
Peoples, Dianna
Peoples, Paul
Poole, Denise
Reed, Ron
Savage, Brandon
Shumaker, Brandon - Manager
Silker, Chad
Stoebick, Roger
Swope, Joseph
Walter, Ruth
Walter, Steve
Williams, Diamond
Witherspoon, Nyla

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): December 7, 2023

Zoetis Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35797	46-0696167
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

10 Sylvan Way Parsippany New Jersey	07054
(Address of principal executive offices)	(Zip Code)

(973) 822-7000

(Registrant's telephone number, including area code)

Not Applicable

(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	ZTS	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On December 7, 2023, the Company declared a dividend of $0.432 per share for the first quarter of 2024. The dividend will be paid on March 1, 2024, to all holders of record of the Company's common stock as of the close of business on January 19, 2024.

The information set forth under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on December 7, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

STATE OF MISSOURI
BOARD OF PHARMACY

OBSERVATION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY OR DRUG DISTRIBUTOR	LICENSE NUMBER	CLASS	INSPECTION DATE
Zoetis US LLC 1100 Main Str., Unit D Lee's Summit MO 64086	2023039647	DD	9/27/2023

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Brandon Shumaker	

PHONE	Fax	Email
8162574346		brandon.shumaker@zoetis.com

INSPECTION TYPE: **Initial**

Inspector: Elaina Wolzak

Acknowledged By: Brandon Shumaker

Observations:

Passed initial inspection.

Comments:

LIMITED POWER OF ATTORNEY

BE IT KNOWN, that Katherine H. Walden, in her capacity as Secretary of Zoetis US LLC, a Delaware limited liability company with principal offices at 10 Sylvan Way, Parsippany, New Jersey 07054, has made and appointed, and by these presents does make and appoint **MR. CHAD SILKER**, as a true and lawful attorney-in-fact for the following specific and limited purposes only:

Application, servicing and renewals of all state licenses, permits, business licenses, and drug and device product registrations required for Zoetis US LLC to operate as a manufacturer and/or wholesale distributor in all states, as required.

This Power of Attorney specifically precludes and limits MR. SILKER's power and authority from receiving, answering or defending any complaint or disciplinary action against Zoetis US LLC by any state or federal authority, but giving and granting said attorney, full power and authority to do and perform all and every act and thing whatsoever necessary to be done in and about the specific and limited premises (set out herein) as fully, to all intents and purposes, as might or could be done if I were personally present, with full power of substitution and revocation, hereby ratifying and confirming all that said attorney shall lawfully do or cause to be done by virtue hereof. This Power of Attorney additionally allows MR. SILKER to request and receive via facsimile a confirmation letter from the Internal Revenue Service confirming this company's federal employer identification number.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 10th day of November, 2017.

Katherine H. Walden

Katherine H. Walden
Secretary

United States of America)
State of New Jersey) ss.:
County of Morris)

On the 13th day of November 2017, before me, Brenda Santuccio, appeared Katherine H. Walden, to me known, who by me duly sworn, did depose and say that she is Secretary of Zoetis US LLC, a Delaware limited liability company, and that she did execute the foregoing document and affixed her signature to the document thereto.

Brenda L. Santuccio
Notary Public

BRENDA L. SANTUCCIO
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2356734
My Commission Expires 3/5/2022

Date: _____

Accepted: Chad Silker, Attorney-in-Fact

LIMITED POWER OF ATTORNEY

BE IT KNOWN, that Katherine H. Walden, in her capacity as Secretary of Zoetis US LLC, a Delaware limited liability company with principal offices at 10 Sylvan Way, Parsippany, New Jersey 07054, has made and appointed, and by these presents does make and appoint **MR. CHAD SILKER**, as a true and lawful attorney-in-fact for the following specific and limited purposes only:

Application, servicing and renewals of all state licenses, permits, business licenses, and drug and device product registrations required for Zoetis US LLC to operate as a manufacturer and/or wholesale distributor in all states, as required.

This Power of Attorney specifically precludes and limits MR. SILKER's power and authority from receiving, answering or defending any complaint or disciplinary action against Zoetis US LLC by any state or federal authority, but giving and granting said attorney, full power and authority to do and perform all and every act and thing whatsoever necessary to be done in and about the specific and limited premises (set out herein) as fully, to all intents and purposes, as might or could be done if I were personally present, with full power of substitution and revocation, hereby ratifying and confirming all that said attorney shall lawfully do or cause to be done by virtue hereof. This Power of Attorney additionally allows MR. SILKER to request and receive via facsimile a confirmation letter from the Internal Revenue Service confirming this company's federal employer identification number.

IN WITNESS WHEREOF, I have hereunto set my hand and seal this 10th day of November, 2017.

Katherine H. Walden
Secretary

United States of America)
State of New Jersey) ss.:
County of Morris)

On the 13th day of November 2017, before me, Brenda Santuccio, appeared Katherine H. Walden, to me known, who by me duly sworn, did depose and say that she is Secretary of Zoetis US LLC, a Delaware limited liability company, and that she did execute the foregoing document and affixed her signature to the document thereto.

Notary Public

BRENDA L. SANTUCCIO
NOTARY PUBLIC OF NEW JERSEY
Comm. # 2356734
My Commission Expires 3/5/2022

Accepted: Chad Silker, Attorney-in-Fact

Date: 16 Nov 17

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Morris & Dickson Co., LLC

Physical Address: 10301 Highway 1 South

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 51367

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Website: www.morrisdickson.com

Name of Designated Representative (DR): Ryan Shane Wagner

Licensing Company Email: licensing@morrisdickson.com DR Email: licensing@morrisdickson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ■ Others: University Veterinary Research Centers	■ Dangerous Drugs ☐ Controlled Substances ■ [a]Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ■ Retail pharmacy wholesale distributor ☐ Others:

[a]Morris & Dickson Co., L.L.C. ("M&D") distributes CDS from it's warehouse in Louisiana to states in which it is licensed to do so. At the present time M&D is not applying for a CDS license in Nevada and therefore will not be distributing CDS into Nevada.

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please See Attached Narrative

Original Signature (electronic, copies or stamps not accepted)

11/22/2023
Date

Morris & Dickson Holding Company L.L.C.

This narrative is submitted by Morris & Dickson Holding Company L.L.C. in connection with its response to Section 8, Questions 5 and 6 on its Personal History Application (the "Application") submitted to the Nevada State Board of Pharmacy.

The owners of M&D Specialty Distribution, L.L.C. ("MDSD") are individuals, partnerships, and L.L.C.s (collectively (the "MDSD Owners"). MDSD, a pharmaceutical wholesaler, has never distributed controlled substances. Some of the MDSD Owners also indirectly are owners of Morris & Dickson Co., L.L.C. ("M&D Co."). M&D Co. is also a pharmaceutical wholesaler, and its business includes the distribution of controlled substances.

Three limited liability companies, WLDT No. 2, L.L.C., WGDT No. 2, L.L.C. MADT No. 2, L.L.C. (together, the "L.L.C.s"), each have an approximate 3.6% indirect interest in M&D through the holding company Morris & Dickson Holding Co., L.L.C. ("Holdco"), which owns M&D Co., and an approximately 11.11% interest in MDSD. Therefore, on the Personal History Application for the L.L.C.s and Holdco, events relating to both MDSD and M&D responsive to Questions 5 and 6 of Section 8 of the Application are set forth below.

Events Concerning M&D Specialty Distribution, L.L.C.

Kansas 2022-12-06 Summary Order, $1,320.00 Civil Fine

In October 2022, MDSD applied to the Kansas State Board of Pharmacy ("KSBOP") for registration as a wholesale distributor. MDSD's license application was granted on December 6, 2022 (a copy of the December 6, 2022 Order is submitted with this Narrative as MDSD Exh. 1). As part of MDSD's license application, it informed KSBOP that between October 2021 and April 2022, prior to MDSD being licensed in Kansas, it had inadvertently shipped a quantity of Rabavert, a rabies vaccine, to an entity in the state. This occurred because Morris & Dickson Co., L.L.C. ("M&D Co."), which was and is licensed in Kansas and has overlapping ownership with and is contractually affiliated with MDSD, had supplied Rabavert to the customer previously. When M&D Co. discontinued the product, the product continued to be available through MDSD, and the Kansas entity ordered the product from MDSD. MDSD then mistakenly shipped the product to Kansas due to an error in software, which should have prevented the shipment to Kansas by MDSD. When MDSD discovered the error, it immediately ceased shipments to the Kansas entity and measures were implemented to prevent a recurrence in that and in all situations. In granting MDSD a wholesaler license in Kansas, KSBOP assessed a civil fine of $1,320.00 for the inadvertent shipments.

* * * * * * * * * * * * * * *

Events Concerning Morris & Dickson Co., L.L.C.

The below information pertains to M&D Co., and not to MDSD.

DEA Proceeding and New Suspicious Order Monitoring and Reporting protocols

Background

On May 2, 2018, approximately five years ago, the DEA commenced an administrative proceeding concerning M&D Co.'s controlled substance registrations (the "2018 Proceeding") by issuing an Order to Show Cause/Immediate Suspension (the "OTSC/ISO") against M&D Co.'s two registrations to distribute

controlled substances (the "DEA Registrations"). Six days later, on May 8, 2018, a federal district court judge issued a temporary restraining order against the DEA, ordering that M&D Co. may resume distributing controlled substances. Shortly thereafter, on May 18, 2018, the DEA ordered that the ISO was rescinded. M&D Co. has been fully operational and its DEA Registrations in place since that time.

The 2018 Proceeding concerned M&D Co.'s suspicious-order monitoring ("SOM") procedures between 2014 and 2018. Following the OTSC/ISO, M&D Co.'s SOM procedures were comprehensively restructured, a state-of-the-art system was implemented, and M&D Co. has operated in complete compliance with federal and state regulations in the half-decade following the OTSC/ISO. It has continued to do so to the present date.

Between May 13-17, 2019, an administrative hearing was conducted before a DEA Administrative Law Judge ("ALJ"). Following the 2019 hearing, and for the past approximately four years, negotiations were ongoing between M&D Co. and the DEA to resolve the 2018 Proceeding and, until May 19, 2023, four years after the hearing, as described below, the DEA Administrator did not issue a final order following the ALJ's 2019 confidential recommendation. During this five year period following the OTSC/ISO, M&D Co. continued to report to the DEA regarding its restructured SOM procedures, which the DEA has described as "impressive." This restructuring is summarized below, followed by a description of the DEA's May 19, 2023 order, which subsequently was amended by a further order from the DEA Administrator, dated May 23, 2023 (the May 19, 2023 order together with the May 23, 2023 order will be referred to below as the "May 19/23 Order").

2018 Restructuring of M&D Co.'s SOM Procedures

The primary basis for the DEA's OTSC/ISO was its view that prior to 2018 M&D Co. had failed to report suspicious orders and to conduct due diligence on certain identified customers. M&D Co. took the DEA's allegations and conclusions very seriously and immediately, in 2018, undertook a restructuring of its SOM procedures. At that time M&D Co. hired the Analysis Group ("AGI"), an experienced data analytics firm with expertise in controlled substance order monitoring to develop a statistical methodology for identifying orders of unusual size, frequency, or pattern. An interim version of the AGI model was put in place on May 24, 2018, less than a month following the OTSC/ISO, and the permanent model was implemented for all retail pharmacy customers on October 1, 2018, alternate care customers in January of 2019 and hospitals in May of 2019. Since the implementation of the interim AGI order monitoring system in 2018-2019, M&D Co. has reported on a daily basis all of the orders flagged by the system to the DEA's complete satisfaction.

In addition, in May 2018, the same month as the OTSC/ISO, M&D Co. hired Guidepost Solutions and its then-Senior Managing Director, Louis Milione to assist M&D Co. in the enhancement of its policies, procedures, and processes related to controlled substance monitoring. The Guidepost personnel were all former DEA Diversion Investigators, former Senior Attorneys, former DEA Special Agents and former state and local law enforcement officials and have been involved in overseeing M&D Co.'s compliance processes since May 2018. Guidepost and members of the M&D Co. Compliance Team have conducted enhanced due diligence, including site visits, on the entirety of M&D Co.'s customer base, which totals over 1,000 customers, with most being the subject of more than one site visit. Since the site visit project began, M&D Co. has terminated the supply of controlled substances to approximately 44 customers and declined to onboard 52 accounts. In August 2021, Mr. Milione left his position at Guidepost to rejoin the DEA as the Principal Deputy Administrator. Presently, Guidepost Senior Managing Director Krista Tongring is M&D Co.'s Interim Chief Compliance Officer.

Further, M&D Co. created an official regulatory affairs group under the leadership of a senior company executive and increased the full-time staff from 1 to its current 11 employees, in addition to Guidepost personnel. In connection with the new regulatory affairs group, M&D Co.'s IT department years ago implemented numerous enhancements to the electronic customer due diligence files from

which the regulatory affairs team makes its order review and other due diligence decisions. Training has been conducted for the new personnel regularly since 2018. All regulatory affairs personnel have been trained on DEA policies and procedures, and several of the team have attended DEA training for wholesale distributor registrants. A written manual of M&D Co.'s Standard Operating Procedures ("SOP") relating to customer due diligence and order review went into effect in May 2019 and was updated in July 2020; SOPs for M&D Co.'s hospital customers went into effect at that time as well.

The DEA Administrator's May 19, 2023 Order and May 23, 2023 Amended Order

In the 2018 Proceeding, on May 19, 2023 the DEA issued a Final Order and then an amended order dated May 23, 2023 revoking the controlled substance registrations of M&D Co. (the "May 19/23 Order," which is submitted with this Narrative as M&D Exh. 1(A)(the May 19, 2023 Order) and M&D Exh. 1(B)(the May 23, 2023 Order) respectively). The May 19/23 Order by its terms did not go into effect until 90 days following the filing of the May 19/23 Order in the Federal Register, which occurred on May 30, 2023. A purpose of the 90-day period prior to the May19/23 Order's effectiveness was to permit the DEA and M&D Co. to negotiate a settlement of the 2018 Proceeding.

The May 19/23 Order was issued five years after the commencement of the 2018 Proceeding, four years after the administrative hearing on the same, and was based solely on events prior to 2018. Furthermore, in the May 19/23 Order, the DEA Administrator determined that since 2018, M&D Co.'s controlled substance policies and procedures were "impressive." Notwithstanding that M&D Co. has been in regulatory compliance since 2018, and will continue to be in regulatory compliance, the May 19/23 Order concluded that M&D Co.'s registrations should be revoked for pre-2018 events.

Fifth Circuit Appeal

On May 30, 2023, before the United States Court of Appeals for the Fifth Circuit (the "Fifth Circuit"), M&D Co. filed a Petition challenging the May 19/23 Order as unjustified and improper. On June 2, 2023, M&D Co. sought a stay of the effectiveness of the Order from the Fifth Circuit for the entire duration of M&D Co.'s appeal (the "Stay Motion").

The Fifth Circuit granted the Stay Motion by Order dated June 16, 2023, (the "June 16, 2023 Stay Order," which is submitted with this Narrative as M&D Exh. 1(C)). The June 16, 2023 Stay Order's effect is to maintain M&D Co.'s DEA Registrations in force during the entirety of M&D Co.'s challenge to the May 19/23 Order. The June 16, 2023 Stay Order was premised upon the Fifth Circuit's determination that M&D Co. was likely to succeed in challenging the May 19/23 Order.

On November 3, 2023, a joint motion was made by the Department of Justice ("DOJ")/DEA and M&D Co. to suspend the litigation of the 2018 DEA Proceeding in the Fifth Circuit (the "Joint Motion to Suspend Litigation") because "the parties are in advanced stages of settlement negotiations and believe that they may be able to resolve the underlying dispute between them." In response to the Joint Motion to Suspend Litigation, on November 8, 2023, the Fifth Circuit issued an Order holding the entire proceeding before the Court in abeyance for a 90 day period "to facilitate settlement discussions" (the "November 8, 2023 Abeyance Order," which is submitted with this Narrative as M&D Exh. 1(D)). If the matter is not settled at the end of the 90 day period, proceedings before the Fifth Circuit would continue. During the entire period and until the end of the litigation, the June 16, 2023 Stay Order also will remain in place.

WDLA Settlement

Additionally, on May 24, 2019, M&D Co. agreed to pay a civil fine of $22 million to the Department of Justice in a settlement reached through the United States Attorney's Office for the Western District of

Louisiana ("WDLA Settlement," which is submitted with this Narrative as M&D Exh. 2). The WDLA settlement, which was not an admission of liability, was finalized and paid in full on May 24, 2019.

Alabama Proceeding

On March 29, 2021, the Alabama State Board of Pharmacy ("AL BOP") issued an Order to Show Cause requiring that M&D Co. show cause why its Alabama state license is relevant to and consistent with public health and safety of Alabama (the Alabama Order to Show Cause is submitted with this Narrative as M&D Exh. 3). The AL BOP attached the WDLA Settlement from 2018 as its only allegation against M&D Co.. M&D Co. opened a dialogue with then-current counsel for the AL BOP and voluntarily provided a litigation history and summary of its compliance program to the AL BOP. M&D Co. explained through written discourse that the WDLA Settlement contained no admissions of wrongdoing by M&D Co. and was simply a "pay for peace" type settlement. M&D Co. requested that the matter be favorably resolved prior to a hearing in light of M&D Co.'s submissions and willingness to be open and forthcoming with the AL BOP. Following the aforementioned dialogue, the AL BOP continued the matter for two years. Recently, new counsel at AL BOP has scheduled a hearing for February 20 2024, wherein, if the matter is not resolved prior to the hearing, M&D Co. will continue to assert that there is not now, nor has there ever been any basis for revocation. Since receiving notice from the AL BOP of the proceeding, in March 2021, M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Alabama and continues to hold that license to date.

Kentucky BOP Letter of Concern

On February 7, 2022, the Kentucky Board of Pharmacy ("KBOP") sent a letter to M&D Co., stating that it had reviewed the WDLA Settlement and the policies and procedures of M&D Co. both before and after the Settlement, and concluded that the issuance of a complaint was not appropriate (the Kentucky BoP Letter of Concern is submitted with this Narrative as Exh. M&D 4). The letter further stated that the KBOP "expressed concern" regarding the WDLA Settlement, but had determined that no other action was appropriate. M&D Co. believes that the February 7, 2022 letter concludes the review of the WDLA Settlement and M&D Co.'s policies and procedures by the KBOP. M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Kentucky and continues to hold that license to date.

Multi-District Litigation

M&D Co. has been named as a "distributor defendant" in approximately 225 cases which have been, or will be consolidated in the United States District Court for the Northern District of Ohio under Multi District Litigation No. 2804, the National Prescription Opiate Litigation. Though the cases are many, the allegations in these cases are materially the same, alleging that the manufacturers of prescription opioids grossly misrepresented the risks of long term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs, all of which contributed to the current national opioid epidemic. M&D Co. has been placed in a small distributors defendants class for purposes of negotiation or litigation, and to date all litigation has been stayed for M&D Co., and for the small distributors defendant class as a whole until resolution of the bellwether trials with the larger defendants has been reached. The complaints do not allege any specific allegations against M&D Co., but rather sweep the entire industry into a set the set of general allegations described above. If and when litigation begins for M&D Co., M&D Co. will deny the allegations alleged in each complaint. M&D Co. believes that the vast majority of this litigation will ultimately be resolved through settlement.

Exhibits to Narrative

Table of Contents

Attachment Pertaining to M&D Specialty Distribution, L.L.C.

MDSD Exh. 1 – December 6, 2022 Order, Kansas State Board of Pharmacy $1,320.00 Civil Fine

* * * * * * * * * * *

Attachment Pertaining to Morris & Dickson Co., L.L.C.

Please see these exhibits attached to the Business Narrative:

DEA 2018 Proceeding

M&D Exh. 1(A) - May 19, 2023 Order

M&D Exh. 1(B) - May 23, 2023 Order

M&D Exh. 1(C) - June 16, 2023 Indefinite Stay Order

M&D Exh. 1(D) – November 8, 2023 Abeyance Order

M&D Exh. 2 - WDLA Settlement

M&D Exh. 3 - AL BoP Order to Show Cause

M&D Exh. 4 - Kentucky BoP Letter of Concern

MDSD Exh. 1 - Kansas State Board of Pharmacy $1,320.00 Civil Fine

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

December 6, 2022

M & D Specialty Distribution, LLC
10301 Highway 1 South
Shreveport LA 71115

RE: Case No. 22-275

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $1,320. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-275
M & D Specialty Distribution, LLC	)	
	)	
Permit 5-119201	)	

SUMMARY ORDER

NOW, on this 6th day of December, 2022, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of M & D Specialty Distribution, LLC. ("Applicant"), for application for registration as a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On October 21, 2022, the Board received Applicant's application for registration as a wholesale distributor in the State of Kansas ("Applicant's Application").

2. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas."

3. In conjunction with Applicant's Application, Applicant provided requested copies of

shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 16 unique days during the previous the time period of October 2021 to April 2022.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Applicant's act of shipping into Kansas prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1627(f).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $1,320. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414,

Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

12/6/2022
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 6th day of December, 2022, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

M & D Specialty Distribution, LLC
10301 Highway 1 South
Shreveport LA 71115

Kansas Board of Pharmacy Staff

Morris & Dickson Co., L.L.C.

This narrative is submitted by Morris & Dickson Co., L.L.C. ("M&D Co.") in connection with its response to Section 2, Question 3 on its Wholesaler Application submitted to the Nevada State Board of Pharmacy.

DEA Proceeding and New Suspicious Order Monitoring and Reporting Protocols

Background

On May 2, 2018, approximately five years ago, the DEA commenced an administrative proceeding concerning M&D Co.'s controlled substance registrations (the "2018 Proceeding") by issuing an Order to Show Cause/Immediate Suspension (the "OTSC/ISO") against M&D Co.'s two registrations to distribute controlled substances (the "DEA Registrations"). Six days later, on May 8, 2018, a federal district court judge issued a temporary restraining order against the DEA, ordering that M&D Co. may resume distributing controlled substances. Shortly thereafter, on May 18, 2018, the DEA ordered that the ISO was rescinded. M&D Co. has been fully operational and its DEA Registrations in place since that time.

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Between May 13-17, 2019, an administrative hearing was conducted before a DEA Administrative Law Judge ("ALJ"). Following the 2019 hearing, and for the past approximately four years, negotiations were ongoing between M&D Co. and the DEA to resolve the 2018 Proceeding and, until May 19, 2023, four years after the hearing, as described below, the DEA Administrator did not issue a final order following the ALJ's 2019 confidential recommendation. During this five year period following the OTSC/ISO, M&D Co. continued to report to the DEA regarding its restructured SOM procedures, which the DEA has described as "impressive." This restructuring is summarized below, followed by a description of the DEA's May 19, 2023 order, which subsequently was amended by a further order from the DEA Administrator, dated May 23, 2023 (the May 19, 2023 order together with the May 23, 2023 order will be referred to below as the "May 19/23 Order").

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Additionally, on May 24, 2019, M&D Co. agreed to pay a civil fine of $22 million to the Department of Justice in a settlement reached through the United States Attorney's Office for the Western District of Louisiana ("WDLA Settlement," which is submitted with this Narrative as M&D Exh. 2). The WDLA settlement, which was not an admission of liability, was finalized and paid in full on May 24, 2019.

Alabama Proceeding

On March 29, 2021, the Alabama State Board of Pharmacy ("AL BOP") issued an Order to Show Cause requiring that M&D Co. show cause why its Alabama state license is relevant to and consistent with public health and safety of Alabama (the Alabama Order to Show Cause is submitted with this Narrative as M&D Exh. 3). The AL BOP attached the WDLA Settlement from 2019 as its only allegation against M&D Co. M&D Co. opened a dialogue with then-current counsel for the AL BOP and voluntarily provided a litigation history and summary of its compliance program to the AL BOP. M&D Co. explained through written discourse that the WDLA Settlement contained no admissions of wrongdoing by M&D Co. and was simply a "pay for peace" type settlement. M&D Co. requested that the matter be favorably resolved prior to a hearing in light of M&D Co.'s submissions and willingness to be open and forthcoming with the AL BOP. Following the aforementioned dialogue, the AL BOP continued the matter for two years. Recently, new counsel at AL BOP has scheduled a hearing for February 20, 2024, wherein, if the matter is not resolved before the hearing, M&D Co. will continue to assert that there is not now, nor has there ever been any basis for revocation. Since receiving notice from the AL BOP of the proceeding, in March 2021, M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Alabama and continues to hold that license to date.

Kentucky BOP Letter of Concern

On February 7, 2022, the Kentucky Board of Pharmacy ("KBOP") sent a letter to M&D Co., stating that it had reviewed the WDLA Settlement and the policies and procedures of M&D Co. both before and after the Settlement, and concluded that the issuance of a complaint was not appropriate (the Kentucky BoP Letter of Concern is submitted with this Narrative as Exh. M&D 4). The letter further stated that the KBOP "expressed concern" regarding the WDLA Settlement, but had determined that no other action was appropriate. M&D Co. believes that the February 7, 2022 letter concludes the review of the WDLA Settlement and M&D Co.'s policies and procedures by the KBOP. M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Kentucky and continues to hold that license to date.

- Morris & Dickson Co., L.L.C.
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BILLING CODE: 4410-09-P

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION MAY 19 2023

Docket No. 18-31
MORRIS & DICKSON CO., LLC
DECISION AND ORDER

On May 2, 2018, the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) and Immediate Suspension of Registration (ISO) to Morris & Dickson Co., LLC (Respondent), of Louisiana. Administrative Law Judge (ALJ) Exhibit (ALJX) 1, at 1. The OSC informed Respondent of the immediate suspension of its Certificates of Registration Nos. RM0314790 and RM0335732 (registrations)[1] and proposed their revocation pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) because it alleged that Respondent's continued registrations were inconsistent with the public interest. *Id.*

Respondent requested a hearing before a DEA ALJ, which was conducted from May 13 to May 16, 2019. On August 29, 2019, the ALJ issued a Recommended Decision (RD), which was transmitted to the Agency along with the administrative record on November 26, 2019.[2] The Agency has incorporated portions of the ALJ's RD herein.

The Government presented a *prima facie* case. Respondent ultimately admitted to and accepted some responsibility for its failures in effectively applying its customer due diligence in assessing orders of controlled substances, its failures to implement a suspicious order monitoring

[1] Respondent sought and obtained a temporary restraining order against enforcement of the ISO. *See* ALJX 89, at 7. On May 18, 2018, the DEA Acting Administrator rescinded the ISO issued on May 2, 2018. Tr. 12; *see Stip.* 26.
[2] On October 8, 2019, Respondent filed Exceptions to the Recommended Decision (Resp Exceptions) and on November 7, 2019, the Government filed a response to Respondent's Exceptions. On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. On January 14, 2022, the Government filed an opposition to this motion and on January 21, 2022, Respondent filed a Reply Memorandum in Support of its Motion to Reopen the Administrative Record. The Agency addresses the Exceptions throughout and the Motion to Reopen at the end of this Decision.

system "consistent with best practices for compliance," and its failures to adequately resolve red flags on orders that it shipped. *See infra* section V. Respondent also admitted that its three suspicious order reports to DEA during the relevant time period were insufficient. *Id.* Nonetheless, Respondent presented testimony and evidence aimed at rebutting the Government's case with regard to the scope of its regulatory noncompliance during the relevant time period.

After thoroughly reviewing the entire record, the Agency finds substantial record evidence that Respondent's continued registration is inconsistent with the public interest in light of the long-term, egregious failures of Respondent in its responsibility as a distributor to maintain effective controls against diversion of controlled substances. Furthermore, the Agency finds that Respondent has failed to demonstrate that the Agency should continue to entrust it with its controlled substance registrations.

I. SUMMARY OF THE ALLEGATIONS

1. The OSC primarily alleged that Respondent failed to maintain effective controls against diversion when it failed to report to DEA thousands of unusually large orders for hydrocodone and oxycodone, which constituted potential suspicious orders, and when it shipped orders to customers without resolving red flags of diversion or reporting the orders to DEA in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1) as well as 21 C.F.R. §§ 1301.71(a) and 1301.74(b). OSC, at 2. Further, the OSC alleged that Respondent failed to adequately design and operate a system to alert Respondent to suspicious orders of controlled substances and failed to report the suspicious orders to DEA in violation of 21 C.F.R. § 1301.74(b). *Id.*

2. The allegations included that, from January 2014 until April 2018, Respondent shipped approximately 7,000 unusually large orders of oxycodone and almost 5,000 unusually

large orders of hydrocodone. OSC, at 5; Govt Prehearing, at 8. During this time, Respondent filed a total of only three suspicious order reports with DEA.

3. Furthermore, the OSC alleged that, from approximately January 2014 to April 2018,[3] Respondent failed to carry out its due diligence and suspicious order monitoring policies and failed to conduct or failed to document the resolution of meaningful due diligence into orders placed by the following pharmacies: Wallace Drug Company, Inc.; Bordelon's Super-Save Pharmacy; Folse Pharmacy; Pharmacy Specialties Group, Inc.; Dave's Pharmacy; the Wellness Pharmacy, Inc.; Wilkinson Family Pharmacy; and Hephzibah Pharmacy, L.L.C. (hereinafter, the exemplar pharmacies).

II. THE WITNESSES

A. The Government's Witnesses

The Government presented its case through the testimony of six witnesses and the introduction of 70 exhibits. The Government's first witness was the Acting Section Chief of the Pharmaceutical Investigation Section of the DEA (the Section Chief), who testified generally regarding the regulatory requirements for distributors. Tr. 47-87. The Government also presented testimony from two Diversion Investigators (DI 1 and DI 2) regarding the history of the investigation and the identification of Government exhibits.[4] *See* RD, at 11-12 (citing Tr. 94-101; 144-177). Next, the Government presented testimony from the Chief of the Statistical Services Section of DEA, G.R., who was qualified without objection as an expert in "developing

[3] The allegations for three of the exemplar pharmacies only spanned a subset of this timeframe: Wellness Pharmacy, January 2014-December 2017; Wilkinson Family Pharmacy, January 2014-April 2017; Hephzibah Pharmacy, April 2017-May 2017. Govt Prehearing, at 3.

[4] The Government presented testimony from a third Diversion Investigator (DI 3) to rebut the testimony of Respondent's witness, however, the Agency agrees with the RD that the testimony of DI 3 was not essential to the case and is therefore not including it herein. RD, at 20.

and implementing statistical models and methods of analyzing large and complex data sets." RD, at 13 (citing Tr. 192). G.R. testified to the methodology he employed in analyzing the statistical data that was used by DEA in its determination that Respondent had failed to report suspicious orders.[5] RD, at 12-15 (citing Tr. 187-245). The Government also presented testimony from the Group Supervisor of the New Orleans Field Division (the GS), who was accepted as an expert in "the identification of common red flags suggestive of an illicit pharmaceutical operation and as well [as] with respect to the requirements imposed on DEA registrants to identify and investigate such red flags when they become aware of them." RD, at 16 (citing Tr. 282).[6]

B. Respondent's Witnesses

Respondent presented its case through the testimony of three witnesses and the introduction of ten exhibits. Respondent's first witness was Kenneth A. Weinstein, Tr. 501-689, who was the Vice President of the consulting firm Analysis Group, Inc. (AGI), and was accepted without objection as an expert in statistical analysis related to controlled substance distribution and in pharmacy ordering and inventory management. RD, at 22 (citing Tr. 513-14; 520-21). Weinstein authenticated Respondent Exhibit (RX) 14, pages 15-19, and RX 28 and 29. Tr. 506, 562-68. Weinstein testified generally regarding the use of the Tukey analytical model in developing Suspicious Order Monitoring systems and testified specifically regarding what he found to be deficiencies in G.R.'s statistical analysis in this case. Weinstein also testified regarding AGI's compliance work for Respondent after DEA had issued the OSC.

[5] G.R. testified that he had corrected DEA's admitted error in the calculations in the OSC, which applied a Three Interquartile Range (IQR) to the median of the data set, or the 50th percentile, instead of the 75th percentile, and as a result, produced a larger group of outliers. Tr. 204, 208-09. G.R. further acknowledged that the error was identified by Respondent's expert. Tr. 218.

[6] The Agency adopts the ALJ's credibility findings regarding the Section Chief, the DIs, G.R., and the GS. RD, at 11-12, 15, 19.

Respondent's second witness was Scott Irelan, Tr. 693-840, who had worked for Respondent for 31 years before becoming the Director of Corporate Compliance and Security in May 2018 after the OSC was issued. Irelan testified regarding his current role at Respondent, the remedial measures that Respondent had put in place since the issuance of the OSC, Respondent's preexisting compliance measures during the relevant time period, and Respondent's acceptance of responsibility.

Respondent's final witness was Louis Milione,[7] Tr. 841-1057, who was, at the time, the Senior Managing Director of Guidepost Solutions. Respondent hired Guidepost Solutions to enhance Respondent's compliance system. Tr. 878-79. Milione was previously the Assistant Administrator of the Diversion Control Division at DEA and was offered and accepted without objection as an expert "in diversion." Tr. 851. He testified regarding his factual interactions with Respondent during his tenure at DEA[8] and regarding the work Guidepost performed for Respondent to improve its compliance with DEA requirements.[9]

III. FINDINGS OF FACT

[7] Milione is currently the Principal Deputy Administrator of DEA. Despite his return to the Agency, it is noted that Milione has not had any contacts with the Administrator nor anyone participating in the decisionmaking in this matter about and due to his prior involvement with this case.

[8] Respondent presented evidence, including testimony from Milione, about a meeting with Respondent at Respondent's invitation that occurred in August 2016 when Milione was in the role of Assistant Administrator of the Diversion Control Division at DEA. Tr. 856-861; RX 21; RX 11 (PowerPoint slide deck). Milione testified that, at that meeting, he believed that Paul Dickson, Sr., was committed to his regulatory obligations and sincere. Tr. 873. The powerpoint slides from that meeting, which Respondent submitted into evidence, generally support Respondent's statements regarding the workings of its previous SOM at a high level and its termination of customers pursuant to its due diligence efforts. RX 11; *see infra* n.61 regarding termination of Respondent's customers, and *infra* n.89 regarding evidence of the sincerity of Paul Dickson, Sr.

[9] The testimonies of Weinstein, Milione, and Irelan are afforded full credibility in this Decision on all points that are within their expertise and relevant to the final decision as further found herein. This Decision has found all major points of conflict between the Government's and Respondent's witnesses to be largely irrelevant to the Agency's adjudication of the allegations. The Agency analyzes the evidentiary weight of portions of the testimony of these witnesses in balance with other evidence on the record where relevant. It is noted that, although Irelan's testimony regarding acceptance of responsibility is analyzed in the Sanction Section *infra*, it is afforded full credibility.

The Parties agree to 47 stipulations (Stips.), which are accepted as facts in these proceedings. The Agency incorporates all of these into the record—the most relevant of which are summarized here. *See* RD, at 33-38. Between January 2014 and May 2018, Respondent submitted a total of three suspicious order reports to DEA. Stip. 7. In this same approximate timeframe, Respondent supplied controlled substances, including oxycodone and hydrocodone, to Wallace, Bordelon's, Folse, Pharmacy Specialties, and Dave's pharmacies. Respondent also supplied Hephzibah with controlled substances, including oxycodone and hydrocodone, between April and May 2017, Wellness Pharmacy between January 2014 and December 2017, and Wilkinson[10] between January and April 2017. *See* Stips. 11-20. The timeframe of the allegations in the OSC are hereinafter referred to as "the relevant timeframe."

A. DEA's Investigation

In 2017, while investigating pharmacies in Louisiana selling high volumes of oxycodone and hydrocodone, the DEA New Orleans Division discovered that some of those pharmacies were supplied by Respondent. Tr. 92. During a subsequent audit, Respondent told DEA that it used Pro Compliance Reports and its employees to identify suspicious orders. Tr. 93.

DEA served Respondent with three separate subpoenas and several requests for clarification between February 1, 2018, and April 2018.[11] RD, at 44-50. The subpoenas related to Respondent's identification of suspicious orders, due diligence, internal investigations, and internal policies and practices, and also identified specific pharmacies. Government Exhibits (GX) 7, 8, 10, 12, 15. Respondent responded via letters and produced some documentation. For example, GX 9 contains an undated letter from Jacob Dickson, stating that Respondent submitted

[10] Wilkinson Family Pharmacy voluntarily surrendered its DEA Certificate of Registration for Cause. Stip. 20.
[11] The Agency adopts the findings of fact in the RD related to these subpoenas and Respondent's response and summarizes herein. RD, at 44-50.

only two suspicious order reports to DEA because it "utilizes a pro-active approach to avoid diversion of controlled drugs, including: screening new pharmacy customers; aggressively monitoring orders for controlled drugs; and eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, fill prescriptions for the 'Holy Trinity' and/or other unacceptable practices." GX 9, at 1; Tr. 319. The undated letter also states that "DEA and applicable regulations do not require that a wholesale distributor maintain records of each and every internal investigation conducted on possible suspicious orders." GX 9, at 1-2 (emphasis in original); Tr. 319-20. The letter further explained that once Respondent has cleared a possible suspicious order, "no record is maintained." GX 9, at 2. The undated letter explained that Respondent used a "four-fold approach to monitor all prescription drug orders and detect unusual ordering patterns, amounts, and cash payments to identify potentially suspicious orders." GX 9, at 2; Tr. 321. The four-fold approach included: use of Pro Compliance Reports; preparing a Market Basket Report of each customer on a monthly basis; since April 2017, use of software that identifies orders that are more than 10 times the "average dosage units ordered on a given drug on a certain day with the last 90 days of ordering patterns of the same drug"; the experience of the employees who fill the orders for controlled substances; and the input of delivery drivers and salesmen. GX 9, at 3-4.

Government Exhibit 11 is Respondent's (signed by Paul Dickson) supplemental undated response to DEA following up on subpoenas issued to Respondent. Tr. 144-45, 324; GX 11, at 2. This response states that "[b]ecause formal records are not kept in the regular course of business on the investigation of orders which do not result in the finding of a 'suspicious order' per 21 C.F.R. § 1301.74, the email communications produced herewith represent the most responsive records maintained." GX 11, at 2; Tr. 324.

At the same time, Respondent produced an external hard drive containing documents in response to the February subpoenas. Tr. 146. Again, DEA emailed Respondent to ensure a complete response, which Respondent generally affirmed and also then provided a phone log[12] with the earliest entry dated January 5, 2016. GX 12-14. In response to the subpoena for policies and trainings, Respondent informed DEA that its training of employees on suspicious order monitoring "does not necessitate or result in the production of documents." GX 16, at 1. Respondent's reply included two policy and procedure documents, which Respondent described as containing "some limited direction as to suspicious order monitoring." *Id.*; Tr. 174-76; GX 17, 18.

B. General Regulatory Obligations

21 C.F.R. § 1301.74(b) requires distributors to

> . . . design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id.

Respondent received a copy of a letter sent on September 27, 2006, by DEA to distributors of controlled substances. Tr. 62-63; GX 3, at 1. The letter emphasized that "[d]istributors are, of course, one of the key components of the distribution chain. If the closed

[12] Regarding the exemplar pharmacies, the phone log contains two entries concerning the Pharmacy Specialties Group, with a DEA registration number ending in "589." GX 14, at 4, 31; GX 23, at 1. Those entries are dated March 7, 2016, and December 13, 2017. GX 14, at 4, 31. There is one entry concerning Dave's Pharmacy, with a DEA registration number ending in "386." GX 14, at 23; GX 24, at 1. That entry is dated February 16, 2017. GX 14, at 23. There are three entries concerning Hephzibah Pharmacy, with a DEA registration number ending in "695." GX 14, at 23, 26; GX 25, at 1. Those entries are dated March 17 and 21, 2017, and June 20, 2017. GX 14, at 23, 26. There are five entries concerning Wilkinson Family Pharmacy, with a DEA registration number ending in "198." GX 14, at 24; GX 27, at 1. Those entries are dated April 19, 20, 21, and 24, 2017. GX 14, at 24. There are three entries concerning Wallace Drugs, with a DEA registration number ending in "363." GX 14, at 31; GX 20, at 1. Those entries are all dated January 9, 2018. GX 14, at 31; RD, at n.12. *See supra* section III.D.

system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." GX 3, at 1. The letter therefore, reminded distributors of their "responsibilities . . . in view of the prescription drug abuse problem our nation currently faces." *Id.* Further, the letter reminded distributors of their duty under the regulation to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and their duty to report suspicious orders to DEA upon discovering the suspicious order. *Id.* at 2. In addition, the letter reminded distributors of their duty to exercise due diligence to avoid filling suspicious orders. *Id.* Finally, the letter provided distributors with 14 examples derived from DEA investigations of a customer's behavior that might be indicative of diversion. *Id.* at 3. The letter states that these examples are not all-inclusive and that "[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. § 823(e)." *Id.* DEA sent the same letter a second time on February 7, 2007. Tr. 64-65; GX 69.

Government Exhibit 4 is a December 20, 2007 letter that the DEA sent to every distributor of controlled substances. Tr. 63-64; GX 4, at 1. The stated purpose of this letter was to again remind distributors of the requirement to inform DEA of suspicious orders. GX 4, at 1. The letter reminded distributors that in addition to "maintain[ing] effective controls against diversion," they are also required to "report suspicious orders of controlled substances." *Id.* The letter reminded registrants that the regulation requires that these orders be reported "<u>when discovered</u> by the registrant." *Id.* (emphasis in original). The letter also reminded distributors "that their responsibility does not end merely with the filing of a suspicious order report.

Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels" in accordance with their requirements to maintain effective controls against diversion in 21 U.S.C. § 823(e). *Id.* The letter also informed registrants that DEA interpreted the list of types of suspicious orders to be "disjunctive and [] not all inclusive." 21 C.F.R. § 1301.74(b).

DEA maintains an Automation of Reports and Consolidated Orders System (ARCOS). Tr. 69-70. Distributors are required to report to ARCOS all shipments of controlled substances in schedules I and II and all narcotic controlled substances in schedule III. Stip. 9; Tr. 70. In April 2008, DEA met with Respondent's President Paul Dickson, Sr., and discussed Respondent's legal obligations and requirements as a distributor, including suspicious order requirements, the need to know its customers, and the need to conduct due diligence. Tr. 67-68. At the time, DEA reviewed its ARCOS data with Respondent to show customers who had anomalies and to demonstrate "things that [Respondent] should be looking at and questioning [its] customers [about]." Tr. 68-69. In 2013 and 2015, DEA conducted distributor conferences and Jacob Dickson, Respondent's compliance officer,[13] attended both conferences. Tr. 66-67. Both sides also presented evidence about a meeting with Jacob Dickson, Paul Dickson Sr., C.G. (a former compliance officer at Respondent) and officials from DEA, including Milione, in which Respondent presented its Suspicious Order Monitoring (SOM) system to DEA. *See* RX 11 (powerpoint); *see supra* n.8.

Respondent filed three suspicious order reports during the relevant time period. Stip. 7. The first, dated April 7, 2014, states that "[a]t this time, and pending further review by you or

[13] The GS testified that "one time [Jacob Dickson] was marked as president and then in the other time it was compliance officer." Tr. 67. In a letter to DEA in response to subpoenas, Jacob Dickson's title was listed as Vice President, SOM Manager. GX 9, at 4.

M&D, M&D has stopped selling schedule II through schedule V drugs to the captioned pharmacy." GX 6, at 1. The next report is dated April 26, 2017, and states that the pharmacy in question "purchased a quantity of 60 cartons of prefilled 10 mg morphine sulphate syringes . . . This was a substantial increase over a total sales of one carton in the prior four months." GX 6, at 35. The letter states that the order was investigated but does not discuss the resolution of this investigation, nor whether the order was filled. *Id.* The final report was filed on the same day, April 26, 2017, and gives no facts related to what order was deemed suspicious nor any information about an investigation or whether the order was shipped. GX 6, at 36.

Distributors are required to design and operate a suspicious order monitoring system that identifies suspicious orders. 21 C.F.R. § 1301.74(b). Suspicious orders include, but are not limited to, three stated criteria: orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.*

Additionally, a distributor's general duty to prevent diversion includes the duty to perform due diligence on its customers. *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,500 (2007); *see also Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,476 (2015), *pet. for review denied, Masters Pharmaceuticals, Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The GS testified that if the required due diligence at the customer level identifies red flags indicative of diversion, Tr. 328, those red flags render an individual order suspicious and trigger the investigation or reporting requirement, even if the regulatory criteria in 21 C.F.R. § 1301.74(b) are not present, e.g., the order size is not unusual. Tr. 477-478; *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (stating that "an order is not only suspicious by virtue of its internal properties—i.e., being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]").

The Agency's decision in *Masters* sets forth that a distributor must either investigate suspicious circumstances on an order and resolve all indicia of diversion or decline to fill the order and report it to DEA. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478.

C. Red Flags—Customer Due Diligence

The record evidence establishes that customer red flags indicative of potential diversion include a pharmacy customer that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail;[14] dispenses disproportionally more controlled substances than non-controlled substances;[15] fills prescriptions for customers who live far away from the pharmacy; fills prescriptions for a high volume of patients who pay for prescriptions in cash;[16] fills prescriptions

[14] The trinity drug cocktail consists of an opioid, such as hydrocodone, a benzodiazepine, such as alprazolam, and a muscle relaxer, such as Soma, and the combination of substances is still a red flag even if each element is prescribed by different prescribers. Tr. 55, 300, 344.

[15] The record contains varying evidence as to the threshold percentage of a pharmacy customer's controlled substance fills relative to its non-controlled substance fills that would trigger a red flag for the distributor. *See* Tr. 351, 461 (The GS testifying that if the percentage of controlled substance prescriptions filled exceeds 15 percent of total prescriptions, it is a red flag); Tr. 1030 (Milione testifying that if a pharmacy is filling controlled substance prescriptions at a percentage exceeding the national average, then the distributor can resolve the red flag without reporting a suspicious order); Tr. 867 (Irelan testifying that the previous SOM system involved monitoring "for customers that were getting a little closer to 20 percent of that ratio"); RD, at n.5 (noting that the *Masters* decision found the threshold to be around 20 percent for controlled versus 80 to 90 percent for non-controlled, *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,480, but finding that the GS presented the most credible evidence at 15 percent).

The Agency finds the exact percentage threshold to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. Furthermore, all of the pharmacy customers in the allegations were dispensing controlled substances at 20 percent or more of their total dispensing—with one customer at one point dispensing as high as 69 percent controlled substances, *see* GX 26, at 11 (Wellness). The only exception was Bordelon's dispensing at 17 percent controlled substances, but which Pro Compliance reported as being "slightly higher than national average." GX 21, at 6. Furthermore, seven of the eight exemplar pharmacies demonstrated multiple red flags in addition to this one. It is indisputable that Respondent was aware of this red flag for each of these customers at a customer level due to the Pro Compliance Reports in its possession.

[16] The record contains varying evidence as to the threshold percentage of cash payments for controlled substance prescription fills at a pharmacy customer that would trigger a red flag for the distributor. *See* Tr. 328 (The GS testifying that any pharmacy customer exceeding 9 percent cash payments from customers should raise red flags); *see also* 1036-37 (Milione testifying that a high percentage of cash in controlled versus non controlled prescriptions is a red flag, but can be resolved with due diligence, the records of which must be maintained); Tr. 681 (Weinstein testifying that if a pharmacy has "a substantially higher percentage of cash payments for controlled substances than it did for a non-controlled substances, that would be a [potential] red flag of diversion," but that he does not have "a particular definition of substantial or significant," because it was more of a "relative comparison"); *but see* Tr. 649 (Weinstein answered that it was "fair" to say that when a distributor becomes aware of factors, such as cash payments, "they're significant red flags of diversion.").

for practitioners whose DEA registrations cannot be verified;[17] fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers; and/or orders excessive quantities of a limited variety of controlled substances. Tr. 297, 299-301, 335, 411, 427, 489-90, 648-49, 681, 1037; *see also* Pro Compliance Reports GX 20-56. Weinstein noted that red flags are visible in a pharmacy's dispensing data and not its ordering data.[18] Tr. 679. Irelan admitted that, during the relevant time period, due diligence was not being applied at the ordering level.[19] Tr. 722-23.

Again, the Agency finds the exact percentage threshold for cash payments to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. As detailed herein, the percentages of cash paid by Respondent's customers at issue were also particularly high, *see, e.g.*, 41 percent, GX 22, at 12 (Folse). It is indisputable that Respondent was aware of this red flag for each of these customers at a customer-level based on the Pro Compliance Reports in its possession.

[17] The Pro Compliance Reports additionally contain reports of prescribers whose DEA controlled substance registrations "could not be verified through DEA-Verify.com" and whose controlled substance prescriptions were filled by Respondent's customers. *See, e.g.*, GX 22, at 17; Tr. 336 (June 2017 Report showing that Folse filled controlled substances prescribed by 23 practitioners whose registrations could not be verified). Both Irelan and Milione testified that the portion of the Pro Compliance Reports concerning the verification of prescriber DEA numbers is unreliable. Tr. 765-66, 797, 901. Milione also testified that a distributor needs to hold and report a suspicious order if it is aware that a customer is filling prescriptions for a practitioner with no DEA registration. Tr. 1025. Although the Agency agrees with the RD, at n.14, that during the relevant timeframe, there is no evidence in the record that Respondent resolved the red flags presented by these reports demonstrating unverified registrations, even if they were unreliable, the Agency also finds that there is more than enough evidence on the record that Respondent did not resolve the other clearly established red flags of diversion and therefore finds it unnecessary to address these additional red flags in this Decision.

[18] The fact that the red flags applied to the customer generally and not to each individual order, *see* ALJX 89, at 99, is irrelevant to this adjudication, because under the relevant legal requirements, Respondent cannot ignore red flags that demonstrate that its customers are potentially diverting controlled substances and continue to fill those individual orders without resolving each of those red flags. *See* Tr. 477-478. At a minimum, Respondent must either have stopped the shipments and reported orders to DEA or resolved and documented each of the red flags. *See Masters Pharm., Inc.*, 861 F.3d at 222-23.

[19] It is noted that Respondent attempted to introduce and the ALJ rejected, Exhibit 32C, based on lack of identification. Tr. 447. Respondent's stated purpose was to impeach the Government's witness in demonstrating that Respondent's due diligence files did include photographs as described in its policy, Tr. 447, contrary to the GS's testimony that he did not "recall any" photographs, Tr. 322; RX 32C. The GS testified credibly that he did not recall seeing the file with the photograph "at all." Tr. 447. The Agency has reviewed the document and notes that it did include a photograph; however, the Agency is not finding that Respondent's compliance with its policy on this issue is relevant to this decision and, therefore, the exhibit marked for identification as RX 32C plays no role in the adjudication of this matter. Further, if this exhibit had been included in the record, standing alone, it bodes poorly for Respondent concerning its failure to report suspicious orders for terminated customers. *See infra* n.61.

The GS testified that when Respondent received the Pro Compliance Reports in GX 20-56 that demonstrated red flags of diversion, it was obligated to resolve the red flags and document their resolution. Tr. 474-76. Based on the record testimony of the experts, and the *Masters* decision, the Agency finds that when a distributor is aware of red flags indicating diversion of controlled substances from a customer, at a minimum, it is obligated to investigate further and resolve the red flags, or, if it chooses not to investigate and resolve, it must report the order as suspicious to DEA and not ship the controlled substances. *See infra*, section IV.A.4.

D. Pro Compliance and Market Basket Reports

In conducting customer due diligence, Respondent used, at least up to and including during the hearing, Pro Compliance Reports,[20] which provide analysis of a pharmacy's dispensing data to include key indicators of red flags of diversion, such as the percentage of a customer's business that represents controlled substance dispensing, the volume of cash payments, and the amount of trinity drug cocktails filled. Tr. 464-65, 716-17. In this case, the reports in Respondent's possession for the exemplar pharmacies demonstrated numerous red flags of diversion, and the Agency finds substantial record evidence that Respondent did not adequately document the resolution of those red flags or report the orders to DEA as suspicious.[21] Additionally, the reports in evidence for the exemplar pharmacies appear to demonstrate violations of Respondent's purported policy of "eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments,

[20] Each Pro Compliance Report contains a statement regarding the Controlled Substances Act (CSA) requirement on manufacturers and distributors to design and operate a system that will disclose suspicious orders of controlled substances. *See, e.g.*, GX 23, at 11; Tr. 355.

[21] Respondent argues that "the Government offered no evidence to demonstrate that Respondent failed to dispel suspicion." ALJX 89, at 100. The Agency finds this argument to be circular. Respondent did not maintain adequate documentation of its resolution of red flags or suspicious orders, so there is no evidence to demonstrate whether it did or did not conduct the due diligence necessary to resolve the red flags. *See infra* n.80. As described herein, the Agency requires documentation of Respondent's due diligence for many reasons.

prescribe the 'Holy Trinity' and/or other unacceptable practices." GX 9, at 1. According to Respondent, Market Basket Reports[22] were prepared for each customer on a monthly basis as part of its due diligence. GX 9, at 3-4. The reports identified percentages of controlled substances in total dispensing. *Id.*; *see, e.g.*, GX 59. Respondent no longer uses Market Basket reports but continues to use Pro Compliance Reports. Tr. 716.

The GS testified that he did not find evidence that Respondent ever rejected a controlled substance order from any of the exemplar pharmacies, nor did he find documentation that Respondent dispelled all of the red flags in these reports. Tr. 385-86, 316,[23] 413.

1. Folse Pharmacy

The record evidence demonstrates that the Pro Compliance Initial Risk Evaluation Report provided to Respondent for Folse Pharmacy designated the pharmacy as "high risk." GX 22, at 5; Tr. 328. Further, Pro Compliance Reports for Folse Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Folse Pharmacy's dispensing practices raised numerous red flags, including: high percentages[24] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[25] an

[22] Respondent points out that the GS's testimony regarding the Market Basket reports was possibly based on a misinterpretation of the numbers. ALJX 89, at 30 (citing Tr. 409, 423-425). In adjudicating the allegations, this Decision focuses on the Pro Compliance Reports in which there is more than enough information to support the Agency's finding that the alleged customers presented red flags of diversion, the resolution of which was not adequately documented, yet Respondent continued to ship. The Market Basket Reports are only considered to demonstrate that Respondent was conducting some due diligence.

[23] Respondent points to Irelan's testimony to contest the notion that Respondent was not stopping shipments based on reports; however, the citations to his testimony support that Respondent was generally conducting some due diligence as it had described in its letters to DEA in response to the subpoena, not that the red flags at issue for the exemplar pharmacies were resolved. ALJX 89, at 16; *see also, e.g.*, RX 31.001 (notes on pharmacies other than exemplar).

[24] According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 30 to 36 percent of Folse's total dispensing. GX 22, at 12-17.

[25] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 18 to 41 percent. GX 22, at 12-14, 17.

increase[26] in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.[27] *See* RD, at 51-53. Furthermore, in June 2017, a Pro Compliance Report recommended that Respondent engage with Folse's owner to "gain a better understanding of [its] dispensing practices . . . ." GX 22, at 17. The record does not include evidence of an investigation into or resolution of the red flags identified. Further, the record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 340; Stip. 13.

2. Bordelon's

Pro Compliance Reports for Bordelon's Super Save Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Bordelon's dispensing practices raised numerous red flags, including: high percentages[28] of controlled substance prescriptions, higher than average oxycodone and hydrocodone units, and dispensing of trinity cocktail prescriptions.[29] *See* RD, at 53-54. In March 2017, a Pro Compliance Report recommended that Respondent engage with Bordelon's owner to "gain a better understanding of [its] dispensing practices . . . ." GX 21, at 6. The record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 347-48; Stip. 12.

3. Wallace Drug Company

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[26] Between September 2013 and November 2014, the number of oxycodone dosage units dispensed increased from 40,812 to 52,571. GX 22, at 12; Tr. 330-31 (The GS describing this increase as "a very big red flag"); *see also* Tr. 471-74.

[27] In June 2017, Folse dispensed nine trinity drug cocktails and in September 2016, Folse dispensed twenty-two trinity drug cocktails. GX 22, at 17, 14; Tr. 300, 335-36.

[28] In March 2017, the percentage of controlled substances dispensed represented 17 percent of Bordelon's total dispensing, which Pro Compliance reported to be "slightly higher than national averages." GX 21, at 5-6.

[29] In March 2017, Bordelon's dispensed four trinity drug cocktails. GX 20, at 5-6.

Pro Compliance Reports for Wallace in Respondent's possession demonstrated that during the time period of the allegations, Wallace's dispensing practices raised numerous red flags, including, but not limited to: high percentages of controlled substance prescriptions paid for in cash,[30] higher than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.[31] *See* RD, at 54-55. In August 2017, a Pro Compliance Report recommended that Respondent engage with Wallace's owner to "gain a better understanding of [its] dispensing practices." GX 20, at 6. Respondent produced phone log entries on January 9, 2018, for Wallace. *See* GX 14, at 31 (note stating that the pharmacy salesman had been contacted and Respondent recommended that he return the order, noting "might need to check on this guy" and "looks like he is hitting this stuff hard!"). Another note on the same date states that the customer was contacted and the customer explained the large order. According to the note, Respondent's employee recommended the return of the hydrocodone and the customer returned it. This note did not occur until five months after the Pro Compliance Report for Wallace, which demonstrated multiple additional red flags of diversion for which there is no documented resolution. Therefore, it is unclear whether the employee flagging this particular order knew that there might be further reason to suspect that this pharmacy was engaging in diversion in order to be able to adequately resolve the suspicious circumstances surrounding the order. Even if this note arguably provided a documented resolution of an unusually large order, the other red flags for this customer are unresolved and unaccounted for. There is also no record evidence that Respondent reported the unusually large order or any orders from this customer to DEA and

[30] In August 2017, 31 percent of controlled substance prescriptions filled by Wallace were paid for in cash. GX 20, at 5.

[31] In August 2017, Wallace dispensed three trinity drug cocktails. GX 20, at 5-6; Tr. 349-50.

there is no record evidence that Respondent stopped shipping to this customer as a result of these reports or notes. Tr. 353; Stip. 11.

4. Pharmacy Specialties Group

Pro Compliance Reports for Pharmacy Specialties in Respondent's possession demonstrated that during the time period of the allegations, Pharmacy Specialties' dispensing practices raised numerous red flags, including: high percentages[32] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[33] an increase[34] in the number of hydrocodone, oxycodone, and benzodiazepine dosage units dispensed, and dispensing of trinity cocktail prescriptions.[35] *See* RD, at 55-57. In February 2016, a Pro Compliance Report recommended that Respondent engage with Pharmacy Specialties' owner to "gain a better understanding of [its] dispensing practices." GX 23, at 6. Respondent's phone logs demonstrate that an employee raised a concern on March 7, 2016, regarding Pharmacy Specialties Group; however, there is no record documentation of how the concern was resolved and Respondent continued to distribute. *See* GX 14, at 4 ("[C]heck out this guys usage for item [] compared to his overall warehouse purchasing, this seems quite elevated to me.....????"). This note identifies a suspicious order; however, according to the record evidence, Respondent did not report the order to DEA. Further, there is no documented investigation or resolution of the concern raised by the employee in the record. On December 13, 2017, another note reads, "Henry will give the customer a warning about his Oxy purchases.

[32] According to the Pro Compliance Reports in evidence, the percentages of controlled substances ranged from approximately 24 to 30 percent of Pharmacy Specialties' total dispensing. GX 23, at 5, 18; Tr. 353-54.
[33] According to the Pro Compliance Reports in evidence, the percentages of controlled substances dispensing paid for in cash ranged from approximately 28 percent to 31 percent. GX 23, at 5-6, 16, 18, 18.
[34] From February 2016 to October 2016, the number of hydrocodone dosage units dispensed increased by 25 percent, while from October 2016 to September 2017, the number of dosage units of oxycodone, hydrocodone, and benzodiazepines dispensed increased by 148, 89, and 106 percent respectively. GX 23, at 16, 18; Tr. 358-59.
[35] In February 2016, October 2016, and September 2017, Pharmacy Specialties dispensed trinity drug cocktails. GX 23, at 6, 16; Tr. 355, 358-59.

Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely." *Id.* at 31. Although this note seems to set forth a plan for compliance, it does not include any indication of an investigation into or resolution of the red flags identified. Further, the record evidence is clear that Respondent did not report this order or any orders from this customer to DEA and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 362; Stip. 14.

5. Dave's Pharmacy

Pro Compliance Reports for Dave's Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Dave's dispensing practices raised numerous red flags, including: high percentages[36] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[37] increases[38] in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.[39] *See* RD, at 57-59. In March 2014, a Pro Compliance Report recommended that Respondent engage with Dave's owner to "gain a better understanding of [its] dispensing practices. . . ."[40] GX 24, at 6. It also states that this pharmacy "represents a relatively ***high risk*** to [Respondent]." *Id.* (emphasis in original). A year later, on February 16, 2017, Respondent's phone logs contain the following

[36] According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 20 to 22 percent of Dave's total dispensing. GX 24, at 5, 18-21, 24, 30; Tr. 362-67.

[37] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 35 percent. GX 24, at 18-21, 23, 24, 30; Tr. 364-67.

[38] For example, from March 2014 to January 2015, the number of oxycodone dosage units dispensed increased from 17,889 to 29,994, and from May 2014 compared to December 2015, the number of dosage units of oxycodone increased by 205 percent. GX 24, at 18, 19, 21; Tr. 364; *see also* RD, at 57-59.

[39] Between March 2014 and January 2015, Dave's dispensed 57 trinity drug cocktails. GX 24, at 18; Tr. 364. Between May 2014 and December 2015, Dave's dispensed 27 trinity drug cocktails, and between December 2015 and June 2016, Dave's dispensed 33 trinity drug cocktails. GX 24, at 19-20. Tr. 365-66. Further, between June and November 2016, Dave's dispensed 37 trinity drug cocktails and in June 2017, Dave's dispensed 14. GX 24, at 21, 24.

[40] This Pro Compliance Report identifies Dave's second highest prescriber as having eighty-five incidents of prescribing trinity drug cocktails.

note about Dave's: "Talked to [D.J.] about the issues at his store. He will let the doctors know that he will no longer be filling these scripts." GX 14, at 23. According to the record evidence, Respondent did not elicit or document an explanation for the red flags and the record is clear that Respondent never reported this order or any orders from this customer to DEA. Further, there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 384-85; Stip. 15.

6. Hephzibah Pharmacy

A Pro Compliance Report for Hephzibah Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Hephzibah's dispensing practices raised numerous red flags, including: high percentages[41] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[42] and dispensing of trinity cocktail prescriptions.[43] *See* RD, at 59-60. In February 2017, a Pro Compliance Report recommended that Respondent engage with Hephzibah's owner to "gain a better understanding of [its] dispensing practices. . . ." GX 25, at 6.

Jacob Dickson sent an email to a DI stating that Respondent had ceased business with Hephzibah because Respondent did not support the customers who "wished to change their business model;" however, Respondent "did not find these accounts to exhibit suspicious activity or excessive orders." GX 72, at 1. Respondent's phone logs state on March 17, 2017, that "they must work on clearing up issues that Pro Compliance found, high cash, trinity & high quantities on Hydrocodone and Oxycodone. Will re-run in 90 days." GX 14, at 23. On March 21, 2017,

[41] In February 2017, controlled substance prescriptions constituted 27 percent of Hephzibah's total dispensing. GX 25, at 6; Tr. 370-71.
[42] In February 2017, the percentage of controlled substance dispensing paid for in cash was 36 percent. GX 25, at 6, 12; Tr. 371.
[43] In February 2017, Hephzibah dispensed nine trinity drug cocktails. GX 25, at 5-6; Tr. 371.

there is a follow up entry that states, "After a couple of months, they decided they would rather change wholesalers than cooperate with our compliance program." *Id.* at 26. Although the notes demonstrate that Respondent was conducting some due diligence, this statement contradicts Jacob Dickson's email asserting that Respondent terminated the business relationship and also that Respondent did not find the accounts to exhibit suspicious activity when it clearly had identified red flags through Pro Compliance Reports. *See* GX 72, at 1 (listing Hephzibah Pharmacy as an account that Respondent "chose to close").[44]

7. The Wellness Pharmacy

Pro Compliance Reports for the Wellness Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wellness's dispensing practices raised red flags of very high percentages of controlled substance prescriptions and high numbers of dosage units of hydrocodone and oxycodone. *See* RD, at 60-61. Although Pro Compliance's initial risk assessment evaluated Wellness as "low risk," it also revealed that between April and June 2013, 67 percent of all prescriptions dispensed by Wellness were for controlled substances. Further Pro Compliance Reports during the relevant time period demonstrated that Wellness's percentage of controlled substance prescriptions continued to range from approximately 64 to 69 percent. GX 26, at 10-12, 14, 21; Tr. 374. There is no record evidence that Respondent reported these orders to DEA or any orders from this pharmacy, documented the resolution of the red flags, or stopped shipping to this customer as a result of the red flags that these reports identified. Tr. 384-85; Stip. 17.

8. Wilkinson Family Pharmacy

[44] The Agency agrees with the ALJ's finding that the phone log note deserves more weight as to what occurred with this pharmacy than Jacob Dickson's email. RD, at 136 n.60.

Pro Compliance Reports for Wilkinson Family Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wilkinson's dispensing practices raised numerous red flags, including: high percentages[45] of controlled substance prescriptions, increases in oxycodone, high percentages of controlled substance prescriptions paid for in cash,[46] higher than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.[47] *See* RD, at 61-63. In January 2017, a Pro Compliance Report recommended that Respondent engage with Wilkinson's owner to "gain a better understanding of [its] dispensing practices." GX 27, at 26.[48] There is no record evidence that Respondent reported these orders or any orders from this customer to DEA, or stopped shipping to this customer as a result of these reports. Tr. 384-85; Stip. 19.

The Government has presented substantial record evidence that Respondent distributed controlled substances to the exemplar pharmacies during the relevant time period in the face of

[45] According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 9 to 42 percent of Wilkinson's total dispensing. GX 27, at 20-23. 25-26; Tr. 367, 378-380.

[46] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 38 percent and cash paid for non-controlled substance prescriptions was significantly lower. GX 27, at 20-23; Tr. 378-380.

[47] Between March 2014 and January 2015, Wilkinson dispensed twenty-six trinity drug cocktails. GX 27, at 21; Tr. 378. Between January 2015 and January 2016, Wilkinson dispensed twenty-one trinity drug cocktails, and between December January 2016, and August 2016, Wilkinson dispensed twenty trinity drug cocktails. GX 27, at 22-23. Tr. 379. Further, in January 2017, Wilkinson dispensed fourteen trinity drug cocktails, and in June 2017, Wilkinson dispensed 14. GX 27, at 26, 32.

[48] Respondent produced an email from March 4, 2014, from Wilkinson, which appeared to be in response to a Pro Compliance Report that Respondent had sent to Wilkinson. Wilkinson's explanation primarily focuses on cash payments. RX 05.001. The GS testified that this showed "some" due diligence. Tr. 452. There was extensive dispute about the introduction of this exhibit during the hearing. Tr. 453-458. It appeared that Respondent did try to offer the exhibit into evidence, Tr. 453, and then offered it subject to connection. Tr. 455. The ALJ ultimately determined to send it to the Agency as part of the administrative record. RD, at 104 n.41. The Agency has considered this exhibit because the contested nature of the hearing at this point has made it difficult to determine whether this exhibit was offered. The exhibit demonstrates that Respondent conducted "some" due diligence on Wilkinson. However, it is noted that the document does not demonstrate the resolution of each of the red flags of diversion, nor does it reflect any independent analysis of Respondent's statements regarding the cash red flag. Ultimately, the Agency accepts that Respondent conducted "some" due diligence for Wilkinson. Further, even if Respondent had adequately resolved the red flags for this pharmacy, there is more than enough evidence of Respondent's failures to conduct due diligence to support the Agency's finding that Respondent's registrations are inconsistent with the public interest.

red flags of diversion, including high percentages of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash, dispensing of trinity cocktail prescriptions, and increases and higher than average dosages of particular schedule II controlled substances. All of these red flags were specifically identified by Pro Compliance Reports in Respondent's possession. Although some of the notations provided by Respondent demonstrated that employees had suspicions about certain orders and had made some contacts, none of the notations adequately resolved the red flags and none of the orders were reported to DEA as suspicious. In the documents Respondent produced to DEA, the GS did not find any indication that the Compliance officer stopped shipment of any order of controlled substances identified as suspicious. Tr. 315-16, 385. It is noted that most of these customers displayed not just one red flag, but multiple red flags of diversion—most of them well over any arguable threshold that would require investigation, *see supra* notes 15-16—and there is insufficient record evidence that Respondent conducted or documented due diligence to resolve these numerous red flags of diversion presented by its customers.

E. Suspicious Orders under 21 C.F.R. § 1301.74(b)

The Government alleged that Respondent failed to design and operate an effective system to disclose to Respondent suspicious orders and to report those orders to DEA. OSC, at 8. DEA used statistical analysis of orders placed by Respondent's customers for oxycodone and hydrocodone to "identify extremely large individual pharmacy transactions and extremely large monthly volume totals," in order to demonstrate the failures of Respondent's SOM system and reporting. *Id.* The GS explained that the reporting of suspicious orders is particularly important for DEA to be able to "conduct an investigation" and identify potential diversion. Tr. 284-86.

G.R. testified regarding the statistical analysis that he performed for the investigation, including his use of a statistical methodology called the Tukey method to identify outlier transactions that represented possible suspicious orders. Tr. 225; 236-37. G.R. testified that Tukey uses an interquartile range, which is the difference between the first and third quartiles, and then is multiplied by a factor of one-and-a-half to six (IQR multiplier). Tr. 202. Although there is no single multiplier to use, Tr. 523, the higher the IQR multiplier, the fewer outliers will be identified. Tr. 523-24. G.R. used an IQR multiplier of 3 to calculate a smaller group of outliers to identify "what are called far out or extreme outliers." Tr. 203, 233, 242. G.R. testified that the transactions that he identified using three IQR above the 75th percentile represented unusually large transactions, which would normally occur less than one percent of the time. Tr. 238-39.

G.R. testified that he analyzed Respondent's sales of oxycodone and hydrocodone from January 1, 2014, to April 30, 2018, and compared every transaction the pharmacy made from January 1, 2014, to April 30, 2018, against every other transaction made during the same time period to the same pharmacy, which he called a "fixed-frame analysis." Tr. 197-98; 226-27. He credibly testified that he used the fixed-frame analysis because he was looking for "a ballpark estimate of scale, size of outlier population," as opposed to the exact number of outliers. Tr. 227, 234.

Government Exhibits 65 and 66 contain all of the transactions concerning oxycodone shipments that Respondent reported to DEA between January 1, 2014, and April 30, 2018, as well as the results of G.R.'s corrected analysis using the above-described methodology. Tr. 71-72. GX 65, 66; Tr. 71-72, 211-12. G.R.'s corrected analysis identified the following amounts of

Respondent's oxycodone and hydrocodone sales as outliers, i.e., unusually large, from January 1, 2014, to April 30, 2018.

Substance	2014	2015	2016	2017	2018[49]	Total
Oxycodone	2,097	1,857	1,546	1,361	391	7,252
Hydrocodone	1,919	1,314	1,006	536	173	4,948

Tr. 212-13; GX 65-66, at Summary tab; Government Demonstrative Exhibit (GDX), at 10.

G.R.'s corrected analysis also identified approximately 450 potential outliers for Respondent's oxycodone and hydrocodone sales for seven[50] of the exemplar pharmacies from January 1, 2014, to April 30, 2018. Tr. 213-14, 216-17, 243; GDX, at 11.[51] *See* RD, at 68 for table. The Agency is considering the review of the exemplar pharmacies' unusually large orders for oxycodone and hydrocodone only to further demonstrate the general failure of Respondent to identify, investigate and report suspicious orders.[52]

In response to criticism from Respondent's expert, G.R. also conducted a "look-back analysis," which, according to G.R., produced results "consistent with what [he] found using the"[53] fixed-frame analysis method. Tr. 228, 235. In his look-back analysis, G.R. looked at "the entire population" and not only the seven exemplar pharmacies in the OSC showing unusually

[49] January 1, 2018, to April 30, 2018. Tr. 212, 226.
[50] G.R.'s corrected analysis did not identify any unusually large transactions of oxycodone or hydrocodone that Respondent shipped to Hephzibah Pharmacy. ALJX 14, at 4; Tr. 230. However, the Pro Compliance Report for Hephzibah Pharmacy demonstrated multiple red flags of diversion. *Supra* section III.D.6.
[51] The tables reflect transaction size, not frequency. Tr. 244.
[52] It is noted that Weinstein conducted a "look-back" analysis of G.R.'s data; Tr. 537-38, 550-51, 693, RDX-4; *see also* RD, at 73 (table analyzing these amounts). The Agency acknowledges that Respondent demonstrated Weinstein's analysis produced significantly lower results; "nearly half of the outlier transactions he identified in 2017 and 2018 would not have been identified as outliers." ALJX 89, at 38 (citing Tr. 529-30, 568; RX 28 and 29)).
[53] Respondent argued in its Exceptions that G.R.'s look-back analysis could not be characterized as "substantially similar" to the fixed-frame analysis because although the numerical size of outliers was similar, each analysis found substantially different outliers. Resp Exceptions, at 41-42. Respondent's point is noted; however, both analyses identified numerous outliers and, ultimately, the number of outliers that could have represented suspicious orders under both analyses far exceeded the three that Respondent reported to DEA during the relevant timeframe. Further, Respondent did not demonstrate adequate documentation of its resolution of suspicious orders nor is there information on the record that Respondent stopped shipping.

large transactions. Tr. 230. G.R. testified that statistical analysis is "one piece of the analysis that is necessary to comply with DEA's regulations governing distributors." Tr. 223-24, 1084-90. *See* GX 73 and 74 (analysis using the look-back methodology that Weinstein recommended). The look-back analysis for oxycodone transactions revealed 6,816 outlier transactions, a 6 percent reduction when compared to the fixed-frame analysis of 7,252 that the Government previously found. Tr. 1091; GX 73, at Summary tab. The look-back analysis for hydrocodone transactions revealed 5,222 outlier transactions, a 5.5 percent increase when compared to the fixed-frame analysis of 4,948 that the Government previously found. Tr. 1092; GX 74, at Summary tab.[54]

Respondent presented the testimony of its own expert, Weinstein, who opined that G.R.'s analysis failed to reliably identify unusually large or suspicious orders. Tr. 558. Weinstein based his criticism of G.R.'s analysis on four factors: 1) the use of a four-year fixed-frame as opposed to the look-back method; 2) the failure to consider the schedule change of hydrocodone in late 2014 from schedule III to schedule II; 3) the failure to consider package size and formulation; and 4) the use of the line item approach as opposed to a cumulative approach. RD, at 70; Tr. 525-28, 541-46, 558.

Weinstein credibly explained his criticisms of G.R.'s analysis in detail, opining that the factors he identified both over-estimated, *see, e.g.*, Tr. 552, and under-estimated, *see, e.g.*, Tr. 552-53, the number of outliers that could have potentially constituted suspicious orders.

[54] Respondent contests the Government's introduction of this rebuttal evidence in its Exceptions. Resp Exceptions, at 40-41. As further explained herein, the Agency credits Weinstein's criticism of G.R.'s analysis. The exact number of unreported suspicious orders is unnecessary for the Government to prove or the Agency to conclude in finding a violation because Respondent was responsible for creating and maintaining an adequate SOM system and identifying and reporting suspicious orders. Here, it is clear from the evidence that Respondent's SOM system during the relevant timeframe was inadequate.

Weinstein notably "did not conduct an original analysis to determine, retrospectively, which of Respondent's orders from 2014 through 2018 should have been identified as suspicious." Resp Exceptions, at 40; *see also* RD, at 25, 75. Respondent argues that it is not Respondent's burden to do so. Resp Exceptions, at 40 (citing *Steadman v. Securities and Exchange Comm'n*, 450 U.S. 91, 100-03 (1981); *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; 21 C.F.R. § 130.44(e)).

Even if the Agency fully credits Weinstein's criticism of G.R.'s analysis, the Government has clearly demonstrated its *prima facie* case that Respondent failed to design and operate a system to identify suspicious orders and report them to DEA and Respondent admits as much. *See, e.g.*, Tr. 666 (Weinstein testifying that the numbers run in early 2018 would have identified suspicious orders in similar quantities to what Respondent is currently reporting); Tr. 813 (Irelan testifying that he accepts responsibility for the Government's allegations in the OSC, paragraph 10, regarding the failure to design and operate an adequate SOM system). The G.R. analysis, according to G.R.'s credible testimony, offered a ballpark estimate of the scale of suspicious orders that Respondent neglected to identify and report to DEA. RD, at 12, and 136; *accord* Tr. 404 (The GS testifying that he asked G.R. to conduct an analysis "to get a sense of just mathematically quantifying how many suspicious orders could theoretically have been missed by Morris & Dickson"[55]). Respondent argued that the Government's case was founded[56] on

[55] It is noted that Respondent uses a different quote from the GS that stated that the intent of the analysis was "to quantify, you know, just how many orders are we talking about that fell outside of just a normal pattern or set amount" and that "the analysis showed that there were roughly, 14,000 orders that should have been reported as suspicious based on the quantity that was ordered." Respondent's Exceptions, at 45 (quoting Tr. 293). Given the several contextual parameters that the GS used in these statements, like "just a normal pattern or set amount" and "based on the quantity that was ordered," the Agency does not find this statement to be inconsistent with the GS's statement at Tr. 404, regarding the purpose of G.R.'s analysis.

[56] The Government's Prehearing Statement states that G.R. "will testify that a standard statistical outlier analysis is a reasonable method to identify unusual transactions in the context of pharmaceutical distribution." ALJX 7, at 6. The description of G.R.'s testimony in both the Government's Prehearing Statement and Third Supplemental Prehearing

establishing specific outliers that Respondent failed report to DEA as suspicious orders. Resp Exceptions, at 43 (citing *e.g.*, OSC, at 37, 46, 54, 65, 74, 84, 93); *see also* ALJX 52, at 20. However, the Agency does not find it necessary to count and identify the exact number of specific outliers, and the reason why is simple. Respondent is charged with violating a non-prescriptive regulation, which clearly places the burden on the distributor to design and operate a system to disclose to the distributor suspicious orders of controlled substances under Agency guidelines.[57] The DEA regulations notably do not prescribe *exactly* what SOM system to use or what constitutes a suspicious order—what constitutes an order of unusual size, an order deviating substantially from a normal pattern, etc. Respondent, in its defense, did not attempt to demonstrate that the system that it had in place during the relevant time period adequately identified suspicious orders—in fact, Irelan took responsibility for Respondent's SOM system failures and failure to adequately report suspicious orders to DEA. Tr. 731, 733. Based on the evidence in the record and Respondent's admitted failures, the Agency finds that Respondent clearly violated 21 C.F.R. § 1301.74(b) in failing to design and operate its system and in failing to investigate or report suspicious orders to DEA. Respondent's attempts to distract the Agency from the notion that it did not adequately meet the regulatory obligation by picking apart DEA's ballpark estimate demonstrating the potential magnitude of Respondent's violations are unavailing. The Agency notes that Respondent contests the quantity of suspicious orders that G.R. identified as unreported to DEA; but G.R.'s analysis, which he notably calibrated to only

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Statement discusses the manner in which G.R. arrived at his calculations and established reasonable thresholds. *Id.* at 6-8; ALJX 52, at 20 ("G.R. will testify that his analysis identified the following unusually large transactions for the exemplar pharmacies."). The Agency additionally agrees with the rationale of the ALJ that G.R.'s testimony regarding the intent of his statistical analysis did not give rise to a new allegation. *See* RD, at 96 n.33.

[57] The December 20, 2007 letter that DEA sent to manufacturers and distributors stated that "[t]he regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders." GX 4, at 1.

identify extreme outliers, Tr. 203, shows that the number of unreported suspicious orders for these two controlled substances during the relevant timeframe could have potentially been in the thousands.[58]

F. Respondent's Policies and Procedures During the Relevant Timeframe

Respondent produced a Policies and Procedure Manual and a Standard Operating Procedures (SOP) Manual in response to DEA's investigation. GX 17 and 18. The Policies and Procedure Manual states, "Where a Compliance Officer sees a ratio of controlled drugs ordered out of the normal range, or the overall quantity is too high compared with the volume of the account, the Compliance Officer has a duty to investigate by calling the account. The Compliance Officer may stop shipment on any order if he or she finds the order to be unusually suspicious." GX 17, at 12. The Policies and Procedures Manual notably does not indicate an obligation to report suspicious orders to DEA. The GS testified that in his review of Respondent's records, he did not see documentation of stopped suspicious orders. Tr. 315-16. The SOP Manual[59] states that Respondent "keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities." GX 18, at 19. The GS testified that this statement does not adequately reflect the obligations in 21 C.F.R. § 1301.74(b). Tr. 307. Further, although the SOP Manual describes various analytical reports regarding drug sales and drug volumes, the GS testified that he did not see any references to these reports in Respondent's relevant records. Tr. 308-09, 491. The SOP Manual does clearly state that "[w]hen a suspicious pattern or

[58] Respondent further made arguments related to what it determined as inconsistent analysis in the RD related to G.R.'s outlier numbers. Resp Exceptions, at 44-46. The Agency finds that G.R.'s analysis provides a ballpark of the egregiousness of Respondent's failures to design and operate the required system. *See* Tr. 227, 224.

[59] The SOP Manual states that the details of Respondent's suspicious order monitoring program "are confidential and therefore are not made a part of this manual." Tr. 306; GX 18, at 17.

purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases,[60] a letter is sent to the DEA indicating a possible suspicious order." GX 18, at 20.

G. Respondent's Former SOM System

Irelan testified that Respondent's SOM system during the time period comprising the allegations (former SOM System) was "not as robust as what we have today." Tr. 738-40 (citing *e.g.*, GX 19, at 3); *see also* RX 31.001 and 31.002 (notes that were part of Respondent's former SOM System). The former SOM system included: know your customer efforts; an electronic customer profile (ECP); a market basket system; reports from Pro Compliance; direct contact with and soliciting of information from customers; and reliance on Respondent's sales force and those who actually filled orders for controlled substances. Tr. 866-70; GX 9, at 2-3; GX 17, at 12; GX 18, at 19-20.

Irelan testified that Respondent's former SOM system would send an email or text message to the compliance officer, C.G., when an order was flagged as suspicious and the order would ship if C.G. did not take action to stop it. Tr. 728, 778.

Irelan testified that Respondent's former SOM system was "not consistent with best practices . . . . because it didn't hold the order. It didn't give an opportunity to resolve red flags before shipping." Tr. 729. Additionally, Irelan testified that "the calculation that the system was using [to identify potentially suspicious orders] was only using ten times a 90-day average," which made it "inadequate." Tr. 729; *see also* Tr. 321-22 (The GS testimony that 8 times the

[60] The GS testified that customers should be contacted in all cases. Tr. 484. *Masters* may provide some room for nuance if Respondent stops shipment of the orders and reports to DEA; however, none of this nuance is represented in the SOP Manual. Additionally, the policy states that "in all cases," DEA is required to be notified, when in fact, DEA was only notified three times during the relevant time period and the record evidence established that Respondent neither reported to DEA nor adequately documented the resolution of red flags for the exemplar pharmacies or generally for suspicious orders during the relevant time period. *See supra* III.D.

average could still be a suspicious order); Tr. 652 (Weinstein testifying that this calculation was not sufficient based on DEA guidance). Regarding the former SOM system, Milione testified that his "understanding is they accepted that there were things wrong with it, that the reporting to DEA was insufficient." Tr. 989. Further, he stated, "it was clear that there was an issue" and that after reviewing the system, his company told Respondent that "there are certain things that should be enhanced knowing what DEA expected." Tr. 990-91. For example, "one of the big things was a way to flag orders [in] real time and in an appropriate way with some kind of an algorithm and then report those flagged orders to DEA." Tr. 991.

Respondent also argues that as a result of its former SOM system, it had ceased supplying controlled substances to 42 pharmacies from 2014 to 2016. RX 11, at 14 (powerpoint slide); Tr. 871. Respondent's expert acknowledged that if those customers had been terminated based on Respondent's SOM program, it should have filed suspicious order reports with DEA. Tr. 1015-16; *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (holding that a distributor discovering a suspicious order must either stop shipping and report to DEA or investigate and resolve the red flags). If Respondent stopped shipping and terminated a customer as a result of discovering a suspicious order, that order should have been reported to DEA. There is no evidence that the 42 customers from 2014 to 2016 were reported to DEA—in fact, the evidence establishes that there was only one suspicious order report filed during this timeframe on April 7, 2014. *See* GX 6, at 1.[61]

[61] It is also noted that Jacob Dickson's letter stated that Respondent had ceased supplying 142 retail pharmacies "due to questions and concerns that the pharmacies were overdispensing controlled substances. After ceasing doing business with these 'bad accounts' [Respondent] has seen very few examples which would justify the reporting of a suspicious order." GX 9, at 5. Milione testified that Mr. Dickson "specifically took pride in being able to say, look, this—every year there has been this—this many customers that they focused on and identified. And I think—I don't know the exact math. It was 125, 135 customers from 2008 to 2016 that were terminated or suspended . . . based upon their compliance suspicious order monitoring program." Tr. 870-71. Respondent provided transcribed testimony from Mr. Dickson in a separate hearing stating that Respondent eliminated 142 customers "because in

H. Respondent's New SOM System

Respondent requested confidentiality related to its current SOM system and policies; therefore, this Decision incorporates by reference the findings of the RD related to Respondent's system and summarizes herein at as high a level as possible while appropriately adjudicating the facts.[62] *See* RD, at 75-82. Guidepost[63] undertook seven corrective measures on Respondent's behalf. Tr. 882. Those measures included: (1) establishing an anti-diversion compliance regulatory affairs team; (2) enhancing Respondent's SOM system; (3) redeveloping Respondent's ECP; (4) enhancing Respondent's "know your customer protocols"; (5) enhancing Respondent's due diligence investigative protocols; (6) conducting employee training; and (7) documenting everything and reporting to DEA. Tr. 882-900. The Analysis Group, Inc., (AGI) was also brought in to develop a live real-time order monitoring system that would identify suspicious orders. Tr. 885. Between May 14, 2018, and July 29, 2018, Respondent submitted 58 suspicious order reports to the DEA. RX 20. In those 58 reports, Respondent informed the DEA

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some form or fashion they might have been suspicious and diverting." RX 1, at 61. It is unclear how many of these customers were terminated during the relevant timeframe—other than the 42 customers that were terminated during 2014 to 2016. Without the benefit of evidence or testimony regarding the circumstances of the terminations during the relevant timeframe, it is difficult for the Agency to determine what weight to give these terminations, *see* RD, at n.32; however, the language on the record describing these orders as "suspicious and diverting" or "overdispensing" or "bad accounts" certainly brings into question whether they could constitute additional violations of the suspicious order reporting requirement. *See also* RD, at 136. In sum, without further evidence explaining the circumstances of the terminations or the reasons why they were unreported to DEA, the Agency cannot give Respondent's terminations during the relevant timeframe the weight that Respondent requests to demonstrate its compliance. These terminations are not being considered as further violations of DEA regulations, but they are also not given weight for Respondent in the public interest inquiry. Finally, the Agency notes that whether Respondent's SOM System was adequate prior to the relevant timeframe is not a matter currently before the Agency.

[62] *See, e.g.*, Tr. 15 (Respondent requesting confidentiality based on "proprietary trade secrets of the Analysis Group regarding the customized suspicious order monitoring system that they have developed for the Respondent, as well as all of the different functionality of the Respondent's suspicious order monitoring system."); ALJX 82. The Agency has provided a high-level summary of these improvements to demonstrate consideration of the scope of Respondent's remedial measures. The numbers of suspicious orders have been included because the Agency finds this information to be relevant to the adjudication of this matter.

[63] Respondent paid Guidepost a large sum of money between the time the OSC/ISO was issued and May 2019 to be brought into compliance with DEA regulations. Tr. 973-74, 992 (*see* RD, at 76 for further details). Milione testified that Respondent has "spared no expense" in becoming compliant with DEA regulations. Tr. 992.

of approximately 3,915 suspicious orders. *Id.* Applying Respondent's new SOM program to its orders from early 2018, Weinstein identified a similar number of suspicious orders.[64] Tr. 666, 676, 682-83. Respondent's current SOM system holds customer's orders as "potentially suspicious" and prevents the orders from being shipped until the Compliance team has reviewed. Tr. 668-69, 672; 582. Furthermore, Respondent currently documents its due diligence regarding suspicious orders in the Enhanced Customer Profiles in a readily-retrievable format. Tr. 737, 716; RD, at 79.

IV. ANALYSIS

A distributor's registration may be suspended or revoked upon a finding that the distributor "has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section . . . ." 21 U.S.C. § 824(a)(4). With regard to distributors of schedule II controlled substances, Congress has set forth five factors to consider when determining whether the distributor's registration would be in the public interest. The factors to be considered are:

> (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
> (2) compliance with applicable State and local law;
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
> (4) past experience in the distribution of controlled substances; and

[64] Although Respondent did not run its new system on the old data during the time period covered by the OSC, Tr. 682, 686, Weinstein did testify that Respondent applied its current SOM system to the orders Respondent received in early 2018 (covering some of the allegations in the OSC) and Weinstein testified that using the current SOM system "[c]ertainly there were some that would have been identified in those months. And in a similar number to what's being identified currently." Tr. 666; *see also* Tr. 676 (data from April 2018 (in the relevant timeframe) produced a roughly similar volume of flagged orders, which "tends to be in the hundreds each month that are identified by the thresholds"). It is noted that these numbers reflect the quantity of orders that would have been flagged for suspicion and does not "take into account any due diligence" etc. Tr. 677. This testimony is not included in this Decision to prove the number of suspicious orders that DEA should have received in early 2018, but, instead, is included to further support the Agency's finding that Respondent's suspicious order monitoring and reporting during the relevant timeframe was insufficient to meet the regulatory requirements.

> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. § 823(b).[65]

The Agency considers these public interest factors in the disjunctive and may rely on any one or a combination of factors and give each factor the weight the Agency deems appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,472 (applying DEA decisions on the public interest factors in 21 U.S.C. § 823(f) to the public interest factors for distributors in 21 U.S.C. § 823(b) and (e)); *see also Southwood Pharm, Inc.*, 72 Fed. Reg. at 36,497-98. Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (1993). There is no need to enter findings on each of the factors.[66] *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005); *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473.

The Government bears the initial burden of proof and must justify revocation by a preponderance of the evidence. *Steadman*, 450 U.S. at 100-03; *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; 21 C.F.R. § 1301.44(e). If the Government makes a *prima facie* case for revocation, then the burden of proof shifts to the registrant to show why its continued registration

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[65] 21 U.S.C. § 823(e) also applies to distributors of controlled substances. The section sets forth the identical factors to be considered regarding a registration to distribute controlled substances in schedules III, IV, and V, as are contained in 21 U.S.C. § 823(b) concerning schedules I and II. The Government's allegations are focused primarily on Respondent's distribution of schedule II controlled substances, but in 2014, during the time period of the allegations, hydrocodone was changed from a schedule III to a schedule II controlled substance. Tr. 539. Additionally, Respondent is a registered distributor of controlled substances in schedules II-V; therefore, the Agency, even when referring only to (b), considers the identical public interest factors under both sections 823(b) and (e) in this section.

[66] Respondent argues that "an independent consideration of each of these [five] factors [at 21 U.S.C. § 823(b)(1–5)] weigh[s] against a finding that Respondent's continued registration is inconsistent with the public interest." ALJX 89, para. 291. In other words, although the Government only submitted evidence relevant to Factor One and Factor Four, Respondent urges the Agency to find evidence relevant to all five Factors. The Agency declines to adjudicate, at Respondent's request, arguments that the Government did not make, yet notes that if it were to do as Respondent requests, the ensuing analysis of all five Factors would continue to point to the revocation of Respondent's registration.

would not be inconsistent with the public interest. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; *see also Med. Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008).

In this case, the Government contends that Respondent's continued registrations are inconsistent with the public interest based on Factors One and Four. ALJ-90, at 27-29.

A. Respondent's Failure to Maintain Effective Controls Against Diversion and its Experience with Controlled Substances (Factors One and Four) [67]

With respect to Factor One, concerning the maintenance of effective controls against diversion, DEA has promulgated regulations to guide the regulated community. Specifically,

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in [21 C.F.R.] §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 C.F.R. § 1301.71(a).

DEA's security regulations further provide that:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).

The OSC alleges that Respondent failed to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," in violation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a). ALJX 1, at 3,

[67] While listing the five public interest factors of 21 U.S.C. § 823(b), the Government specifically notes that it does not rely on Factors Three or Five and makes no argument concerning Factor Two. ALJ-90, at 27-29 & n.12. Further, the Government combines its analysis of Factors One and Four. *Id.* at 28-44. The Government notes that where it has not made allegations with respect to Factors Three and Five, the factors do not weigh for or against revocation. *See* ALJX 90, at n.12. As such, although the Agency has considered all five factors, its analysis focuses on Factors One and Four.

paras. 7, 10. Second, the OSC alleges that Respondent failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report them to DEA, in violation of 21 C.F.R. § 1301.74(b). ALJX 1, at 3, paras. 8, 10.

Factor Four involves a registrant's past experience in the distribution of controlled substances, which the Government has argued is appropriately considered along with its maintenance of effective controls against diversion. *See, e.g., Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473. In this case, Respondent argues that its experience in the distribution of controlled substances "is extensive," as it was "founded in 1841 and distributes more than 33,000 products," and that its history of compliance weighs against a finding that Respondent's registration is inconsistent with the public interest. ALJX 89, at 115-116 (citing RX 1, at 13:16, 15:10). Although Respondent's arguments have been considered, Respondent's misconduct as described further herein precludes a finding that Respondent's experience establishes a "history of compliance." *See Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, 52,702 (2008) (analyzing the identical factor for distributors under 21 U.S.C. § 823(h)).

1. A Suspicious Order

To begin, the regulations require distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). The regulations provide that, at minimum, a suspicious order includes "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*; *see* section IV.A.3. These three criteria are non-exclusive and registrants may encounter other considerations beyond those spelled out in the regulation that could qualify an order as suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473-74; *Masters Pharm., Inc.*, 861 F.3d at 221 (noting the regulatory criteria for suspicion are "exemplary rather than exhaustive"). For

example, a distributor might find a pharmacy's orders for controlled substances to be suspicious not only based on their exhibiting the characteristics set forth in the regulation, but also based upon the "pharmacy's business model, dispensing patterns, or other characteristics." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473-74; *see also id.* at 55,477 (stating that "an order is not only suspicious by virtue of its internal properties—i.e., being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]"). The identification of a suspicious order that is based on the nature of the pharmacy's business takes place at the customer-level. *See infra* section IV.A.4.

In order to conclude that an order for controlled substances is suspicious, a "distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,480. In fact, suspicion is a low standard, defined as merely one's "'apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478 (quoting Black's Law Dictionary 1585 (9th ed. 2009)). Thus, if a distributor is aware of any indication of "the existence of something wrong" concerning the size, frequency, or pattern of an order, then the distributor is obligated to report it to the DEA. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478. Because suspicion is a low standard, a distributor's obligation to report suspicious orders is triggered long before the distributor would have probable cause to believe that a customer is engaged in diversion. *Id.* As *Masters* explains, suspicion is not contingent on evidence that the order will be diverted or that the customer is engaged in diversion. *Id.* With regard to the reporting requirement, the Agency's emphasis is on *suspicion* and not conclusive proof of diversion. *Id.* at 55,420 (explaining that tying suspicion to

evidence of diversion "imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious").

2. Respondent's Failure to Adequately Design and Operate a Suspicious Order Monitoring System.

When a distributor's suspicious order monitoring (SOM) system places a hold on a customer's order for controlled substances because the order is of unusual size, pattern, or frequency, the order meets the specific criteria of being suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,479; *Masters Pharm., Inc.*, 861 F.3d at 216-17 (affirming the Acting Administrator's ruling that "orders held by the [distributor's SOM systems] met the regulatory definition of 'suspicious orders'"). DEA has made clear that it does not endorse any particular system for identifying suspicious orders. GX 4, at 1; Tr. 59-60, 76, 210, 497, 646.

In this case, Respondent's SOM system during the relevant time period did not have the capability to hold an order that was flagged as "potentially suspicious." Tr. 728, 778. Therefore, the system could not comply with the DEA legal requirements. Tr. 729 (Irelan testifying that the SOM system was "not consistent with best practices" because "[i]t didn't give an opportunity to resolve red flags before shipping.")

Additionally, the witnesses were in agreement that Respondent's SOM system during the relevant time period was inadequate to identify orders of unusual size in that it only flagged orders that were "ten times a 90-day average," Tr. 729-30, 321, 652.[68]

Further, while Respondent had written policies and procedures, those policies and procedures only identified three suspicious orders over a period of four years and four months that were reported to the DEA. Respondent admits that its previous policies were inadequate.

[68] DEA sent a letter in December 20, 2007, warning distributors that a SOM system "rely[ing] on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." GX 4, at 2.

Tr. 720-21. Respondent had a policy of producing monthly and daily reports, yet none is apparent in the Administrative Record, and although Respondent maintained a proprietary database, RX 11, at 5, there is no record evidence from this database.

Finally, although Respondent argues that the record supports that it was conducting due diligence into its customers, Respondent admits that it did not adequately document that due diligence, nor did it apply that due diligence at an order level. *See infra* section IV.A.4. Respondent's policy of not documenting its due diligence, GX 9, was also inconsistent with the *Masters* decision. *See id.*

In sum, the Agency finds substantial record evidence that Respondent failed to design and operate an adequate SOM system in violation of 21 C.F.R. § 1301.74(b).

3. Respondent's Failure to Report Suspicious Orders under the Listed Criteria in 21 C.F.R. § 1301.74(b)

As explained above, DEA regulations obligate distributors of controlled substances to not only design and operate a system to identify suspicious orders, but to also report all suspicious orders to DEA. 21 C.F.R. § 1301.74(b). In other words, DEA regulations require distributors like Respondent "to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally." *Masters Pharm., Inc.*, 861 F.3d at 217-18 (emphasis in original).[69] Moreover, the Agency has previously held that filing ARCOS reports does not satisfy a distributor's obligation to notify DEA of suspicious orders, *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,501, nor does filing reports on a routine or periodic schedule. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478.

[69]Suspicious orders meeting the definition in 21 C.F.R. § 1301.74(b) must be reported to DEA, and Respondent did not argue otherwise. *See, e.g.*, Tr. 732, 1024; RX 20.001, at 1. There is additionally no record evidence that Respondent investigated these suspicious orders and resolved them at any time.

The purpose of the DEA's reporting requirement is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,483 n.169 (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,501). As such, when a distributor obtains "information that an order is suspicious but then chooses to ignore that information and fails to report the order," the distributor violates its regulatory obligation. *Id.* at 55,478.

Here, DEA presented evidence using the Tukey statistical model to determine a ballpark number of suspicious orders that an adequate SOM system might have identified during the time period in the allegations both for the eight exemplar pharmacies and for Respondent's customer base at large for two frequently abused controlled substances: oxycodone and hydrocodone. The ballpark estimate found numerous potential suspicious orders for seven out of the eight exemplar pharmacies, and for the overall customers, it found that 7,252 sales of oxycodone and 4,948 sales of hydrocodone during this time period should have possibly been reported as suspicious to DEA.[70]

The ballpark numbers constitute substantial evidence that there were far more suspicious orders that should have been identified, investigated, or reported than the mere three that Respondent reported during the time period. Even taking into consideration all of the criticism levied on DEA's modeling by Respondent's expert, he himself admitted that the data run during the beginning of 2018 produced similar results to the quantity that Respondent was reporting under the new system, which, in a little over a year, amounted to 3,915 suspicious orders. As such, the Agency agrees with the ALJ that the three suspicious order reports filed during the

[70] It is noted that the ballpark numbers that G.R. testified to support a conclusion that Respondent failed to identify, resolve, or report suspicious orders under the criteria in § 1301.74(b) to DEA—not whether Respondent failed to conduct customer due diligence generally.

relevant timeframe "barely scratched the surface," RD, at 140, and finds it clear that the Government has proven by substantial evidence that Respondent failed to investigate or report potentially thousands of suspicious orders of oxycodone and hydrocodone to DEA. *Supra* section III.E.

Furthermore, the *Southwood* decision explained that even *after* a suspicious order is reported to DEA, a distributor must conduct some due diligence and only ship the order "if it is able to determine that the order is not likely to be diverted into illegal channels." *Masters Pharmaceuticals*, 861 F.3d 206 (2017) (citing *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,500). Here, it is undisputed that Respondent submitted three suspicious order reports to DEA during the relevant time period. The GS testified that Respondent shipped these orders without documenting any resolution of the suspicious circumstances that caused Respondent to report them to DEA. Tr. 294. Thus, the Agency finds substantial record evidence that Respondent's lack of documentation of its investigation into and resolution of these red flags, coupled with its shipping of the suspicious orders, demonstrates additional violations of Respondent's regulatory obligations to provide effective controls and procedures to guard against diversion of controlled substances.

4. Customer Due Diligence and Red Flags

It is inherent in the obligation under 21 C.F.R. § 1301.71(a) to maintain "effective controls" against diversion that "a registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of [their controlled substances] sales." *Holloway Distributing*, 72 Fed. Reg. 42,118, 42,124 (2007).[71] Therefore, a distributor is required to act on

[71] *See also Holloway Distributing*, 72 Fed. Reg. 42,118, 42,124 (2007) (finding that a distributor of List I chemicals' "policy—which is fairly characterized as 'see no evil, hear no evil'—is fundamentally inconsistent with the obligations of a DEA registrant").

"'information which raise[s] serious doubt as to the legality of [the customer's] business practices,'" also referred to as red flags,[72] indicative of diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,498). A distributor must also "conduct a reasonable investigation to determine the nature of a potential customer's business before it sells to the customer." *Id.* Furthermore, a distributor has a continuing obligation to perform due diligence of a customer throughout the distributor's relationship with that customer. *Id.* at 55,477. *Masters* clarified that "although a distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicating that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order." *Id.* at 55,478.

The record evidence and testimony from multiple experts in this case, the Pro Compliance Reports themselves, and prior DEA decisions have all clearly demonstrated that such suspicious circumstances, or red flags, include a pharmacy that: dispenses a high volume of narcotics;[73] dispenses the trinity drug cocktail;[74] dispenses disproportionally more controlled

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[72] It is noted that Agency Adjudications have used the term "red flag" as early as 1998 and federal courts have used the term as early as 1986. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,195 n.23 (2016), *pet. for rev. denied*, 881 F.3d 823 (11th Cir. 2018). In general, a red flag is any "circumstance that does or should raise a reasonable suspicion as to the validity of a prescription [or order]." *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. at 10,896 n.31 (quoting *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. at 49,839). Red flags are, in essence, "warning signs" or "suspicious circumstances" that alert the registrant that something is not right. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,195 n.23.

[73] *Masters Pharm., Inc.*, 80 Fed. Reg. at 5548-81 n.168 (explaining where a distributor had information that 50 percent of the prescriptions filled by a pharmacy were for controlled substances, while the average pharmacy only fills about 20 percent, the distributor "had substantial information which raised a strong suspicion as to the legitimacy of [the pharmacy's] dispensing practices"); GX 3, at 3.

[74] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,194 ("The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,163 (2010))).

substances than non-controlled substances;[75] fills prescriptions for a high volume of patients who pay for prescriptions in cash;[76] fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers;[77] and orders excessive quantities of a limited variety of controlled substances.[78] *See supra* section III.C. A distributor fails to maintain effective controls against diversion when the distributor continues to distribute controlled substances to a pharmacy that exhibits red flags of diversion without resolving those red flags. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,457 (faulting the distributor for supplying controlled substances "while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances"); *cf. Top RX Pharmacy*, 78 Fed. Reg. 26,069, 26,082 (2013) (applying a similar principle to pharmacies filling prescriptions that contain red flags of abuse or diversion); *see also Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, 52,699 (2008) (applying a similar principle to list I chemical distributors under 21 U.S.C. § 823(h) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")).[79] A distributor

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[75] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,456; GX 3, at 3.

[76] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,194 ("'[A]ny reasonable pharmacist knows that a patient that (sic) wants to pay cash for a large quantity of controlled substances is immediately suspect.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,158 (2010))).

[77] GX 3, at 3.

[78] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,421; GX 3, at 3.

[79] Respondent introduced testimony regarding whether Respondent could continue to ship during a due diligence investigation into customer-level red flags of diversion—arguing that there is a certain amount of discretion involved and that stopping shipments would disrupt the supply chain. *See, e.g.*, Tr. 1049, 1050, 1042; 649. The record does not support a finding that Respondent did, in fact, adequately dispel all of the red flags on these customers at any time (before or after distributing), or that Respondent adequately documented purported resolutions of the red flags. The *Masters* decision cannot be read to intend to create a loophole in which a distributor could avoid reporting requirements and continue to ship orders of controlled substances while conducting lengthy investigations into red flags. Such an interpretation would not meet the requirement that a distributor maintain effective controls against diversion. To the extent that, as Respondent argues, there may be some discretion in the

has an obligation to guard against diversion, and as such, must resolve red flags of diversion presented by its customers or decline to ship the controlled substance. 21 U.S.C. §§ 823(b), (e); 21 C.F.R. § 1301.71(a).

When a customer demonstrates red flags of diversion, the distributor must report a suspicious order to DEA unless the distributor conducts a due diligence investigation, which "must dispel all red flags indicative that a customer is engaged in diversion." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478. "Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the [DEA] must be informed." *Id.*; *see also id.* at 55,479 n.164 (same).

In upholding DEA's interpretation of the due diligence requirement in the *Masters* decision, the D.C. Circuit Court of Appeals stated:

> As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like the SOMS Protocol to guide its efforts, then the distributor must actually undertake the investigation. For example, when an employee uses the SOMS Protocol to confirm or dispel suspicion based on the amount of controlled medication the pharmacy is selling, the employee must request a 'UR,' *i.e.*, a document showing the pharmacy's 'actual dispensing[s] . . . of each drug.' [*Masters Pharm., Inc.*,] 80 Fed. Reg. [55,418,] 55,420 [(2015)]. Moreover, the investigating employee must 'document' customers' explanations for suspicious orders, so that he or she can verify those explanations and make sure they are consistent over time. *Id.* at 55,428 n.21. Additionally, if a customer's explanation for its order is 'inconsistent with other information the investigator has obtained about or from

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decision of when to ship, it is abundantly clear that a distributor cannot ship if it cannot determine that the "proposed transaction is for legitimate purposes," *Novelty Distributors* 73 Fed. Reg. at 52,699, or without resolving "'information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,498). Further, Respondent's supply chain argument is weakened by the fact that Respondent had a duty to and was purportedly running reports on prospective customers; therefore, it knew about many of the red flags in the eight exemplar pharmacies before engaging in business with them. *See, e.g.*, GX 25, at 4 (Initial Risk Evaluation Report for Hephzibah Pharmacy LLC); RX 11, at 15 (powerpoint demonstrating turned down prospective accounts based on Pro Compliance Reports).

> the customer, . . . the [investigator] must conduct 'additional investigation to determine whether [its customer is] filling legitimate prescriptions.' *Id.* at 55,477. Finally, the investigation must dispel all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances. *Id.* at 55,478. The Administrator recognized that, if investigating employees fail to take such basic steps, the SOMS (or similar protocol) does not function as an effective tool for dispelling suspicion.

Masters Pharm., Inc., 861 F.3d at 222-23. The D.C. Circuit made clear that all red flags must be resolved or the order must be reported to DEA as suspicious.

In this case, Respondent received numerous Pro Compliance Reports that raised multiple red flags for each of the relevant customers during the relevant time period. *See* GX 20-56; *supra* section III.D. The Pro Compliance Reports themselves clearly identify specific red flags in Respondent's customers' data and frequently recommend further discussions and onsite visits to resolve them. *See, e.g.*, GX 21, at 6; *supra* III.E. Although Respondent produced some minimal evidence consisting of phone logs for some of the exemplar pharmacies in the OSC, *see supra* n.12 and section III.D., which indicated a few instances over the several year timeframe where Respondent had engaged with these customers regarding red flags and/or suspicious orders, there is not adequate documentation as to how Respondent resolved the red flags, even as Respondent continued to fill these orders without reporting them to DEA. Moreover, the GS credibly testified that documentation was an essential component of due diligence. Tr. 298-99 ("[I]f you don't document it how are you going to remember it, how are you going to be able to prove it happened"). The *Masters* decision further pointed out that documentation is essential in maintaining effective controls against diversion to ensure that customers are consistent in their explanations regarding red flags. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,428 n.21. The D.C. Circuit also affirmed the Agency's position that if a distributor undertakes an investigation into its customer's potential diversion, then it must document and "dispel all of the 'red flags' that

gave rise to the suspicion that the customer was diverting controlled substances" to avoid the requirement to report the suspicious order to DEA. *Masters Pharm., Inc.*, 861 F.3d at 222-23.

Here, Respondent acknowledged the paucity of documentation in its records that might show that it had resolved red flags. *See, e.g.*, Tr. 720; GX 9, at 1-2. Contrary to Respondent's argument (ALJ-89, at 101-03, paras. 272-75), the absence of documentation of resolving red flags does indeed constitute evidence that the red flags were never resolved. *See Masters Pharm., Inc.*, 861 F.3d at 218.[80] While Respondent did conduct some due diligence, such as by obtaining Pro Compliance Reports and by preparing its own monthly Market Basket Reports of its customers, ordering the reports without taking appropriate action based on the content of those reports does not come close to satisfying the regulatory obligation to conduct due diligence. These Pro Compliance Reports identify multiple red flags from Respondent's pharmacy customers—demonstrating that Respondent was aware of these red flags—while the records it produced do not resolve them in any substantive way to demonstrate effective controls against diversion. *See, e.g.*, GX 20-56 (the Pro Compliance Reports for the exemplar pharmacies). Respondent's employees even noted occasions where information in the Pro Compliance Reports was specifically concerning to them or where they were aware of additional

[80] To permit Respondent to escape any liability for its lack of adequate controls to protect against diversion merely because Respondent created a policy that did not require documentation of how those controls were exercised would nullify the purpose of the statutory and regulatory requirements. Further, the Agency agrees with the ALJ that Respondent's intentional strategy of not presenting the testimony of any witness who was actually involved in Respondent's purported resolution of red flags further undermines its argument that the red flags were actually resolved. *Id.* Finally, Agency decisions have frequently described the importance of documentation to meet DEA regulatory requirements in other contexts. *See Kaniz F. Khan-Jaffery, M.D.*, 85 Fed. Reg. 45,667, 45,686 (2020) ("DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment." (citing *Cynthia M. Cadet, M.D.*, 76 Fed. Reg. 19,450, 19,464 (2011))). In particular, the *Masters* decision affirmatively stated the requirement for distributors to document their resolutions of red flags and gave a rational basis for that requirement—ensuring that the information is memorialized for the resolution of future indicia of diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,428 n.21. This basis is very apparent here where Respondent's customer base is large and the shipments are numerous. As such, the Agency finds that Respondent's failure to maintain adequate documentation indicates a violation of the requirements to maintain effective controls against diversion.

indicia of diversion or suspicious orders, yet these orders were neither reported to DEA nor is there record evidence to support a finding that Respondent resolved all of the red flags that gave rise to the suspicion. *See, e.g.*, Respondent's employee's comments, at GX 14, at 4 ("[T]his seems quite elevated to me.....????") and 31 ("Henry will give the customer a warning about his Oxy purchases. Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely."). The note documenting this interaction not only fails to offer any resolution of the suspicious circumstances or indicate any reporting to DEA, but also indicates that Respondent knew of the existence of a suspicious order and that the customer was given a warning—providing it with a chance to amend its behavior and further avoid detection from DEA. The regulations require resolution or reporting, not implementation of a "second chance" or "three strikes you're out" program.

A distributor fails to conduct meaningful due diligence that satisfies its regulatory duties where it merely "accept[s] at face value whatever superficial explanation" the pharmacy offers and then fails to independently verify it. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,457. Further, conducting due diligence but then failing to act on the findings is also inadequate. *See Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,500 (finding the distributor's due diligence efforts to be inadequate where the distributor possessed information that customers were diverting controlled substances yet the distributor continued to provide them with controlled substances). Thus, as the GS credibly testified as an expert witness, the Agency finds that even though Respondent produced some due diligence files to DEA, Respondent seemed to "conduct due diligence and ignore the red flags that are in [its] face and continue to ship" without documenting the resolution of red flags or reporting to DEA, in violation of DEA regulations. Tr. 463; *see also* Tr. 80 (testimony of the Section Chief: "[Y]ou can ask for all these things, but you have to

do something with it."). As the evidence shows, Respondent continued to distribute controlled substances despite the red flags raised in its due diligence files and without either adequately documenting an investigation or resolution of the red flags or refusing to ship and reporting the orders to DEA. As such, Respondent's due diligence was clearly insufficient to meet DEA's legal requirements. *See also* RD, at 120-128 (finding that Respondent did not either dispel all red flags for Folse, Bordelon's, Wallace, Pharmacy Specialties, Dave's Pharmacy, Hephzibah, Wellness, and Wilkinson or report the customers to DEA and refuse to ship).

5. Summary of Public Interest Factors

There is substantial record evidence that Respondent failed to adequately design a suspicious order monitoring system and failed to report suspicious orders to DEA. Further, Respondent failed to report controlled substance orders from customers displaying red flags of diversion and in such cases failed to either cease shipment, or, alternatively, to investigate, resolve, and document the resolution of the red flags. Thus, the Agency finds that Respondent failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels in violation of 21 C.F.R. § 1301.71(a). The Agency also finds that Respondent failed to adequately design and operate a system to disclose to the registrant suspicious orders of controlled substances and report those orders to DEA in violation of 21 C.F.R. § 1301.74(b). *See also* RD, at 138. These violations constitute failures to maintain effective controls against diversion under 21 U.S.C. § 823(b)(1) and demonstrate negative experience in distribution under 21 U.S.C. § 823(b)(4) and weigh strongly in favor of revoking Respondent's Certificates of Registration.

B. Respondent's Integrated Enterprise

DEA has requested revocation of both Respondent's registration at its distribution center in Shreveport, Louisiana, and Respondent's second registration in New Orleans (Jefferson Parish). Respondent argues that DEA has not "alleged any misconduct to have occurred at Respondent's Jefferson location or adduced any evidence or testimony at the hearing regarding Respondent's Jefferson registration." Resp Exceptions, at 49.

The Agency has frequently "treat[ed] two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,222 (2016) (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71,956, 71,958 (2007)). "[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy." *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,341, n.71 (2016). Further, the Agency may revoke a registration without misconduct attributable to that particular registration if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.*, 82 Fed. Reg. 21,410, 21,430 (2017) (revoking physician's DEA registration in Florida due to conduct attributed to a Texas registration that had expired).

When a practitioner registrant acts in a manner inconsistent with the public interest, in determining whether to revoke, DEA looks to whether the practitioner can be entrusted with a registration. *See, e.g. Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016). If a practitioner holding multiple registrations cannot be entrusted with one, then it would be difficult to justify entrusting the same practitioner with another in a separate location. Similarly, when a corporate

entity is owned and operated by individuals who have acted inconsistently with the public interest and have misused one of their registrations, the Agency cannot ignore this fact when considering whether to entrust those same individuals with another registration. Furthermore, even if Respondent has not used the Jefferson registration for distribution, this fact does not prevent it from using its registration for distribution in the future.[81] *See Suntree Pharmacy and Suntree Medical Equipment, LLC*, 85 Fed. Reg. 73,753, 73,766 (2020).

The lens through which Congress has instructed the Agency to assess each distributor registration is whether or not such registration is consistent with the public interest. 21 U.S.C. § 823(b). In this case, if Respondent was allowed to simply shift its operations to an entity with the same ownership, then the effect of the violations found herein against Respondent would be a nullity and there would be nothing to prevent Respondent's Jefferson location from continuing to act inconsistently with the public interest. It would be inconsistent with the intent of the CSA to permit such an easily implementable loophole, while it is consistent with Agency decisions to close the loophole by treating the two overlapping entities as one integrated enterprise for purposes of sanction.

Therefore, due to the uncontested commonality of ownership, management, and operations, *see* RD, at 154, the Agency finds that it is appropriate to treat Respondent's two registrations as one integrated enterprise.

V. SANCTION

The Government has established a *prima facie* case to revoke Respondent's registration; therefore, the Agency will review any evidence and argument that Respondent submitted to determine whether or not Respondent has presented "sufficient mitigating evidence to assure the

[81] The ALJ noted that Respondent's exhibits demonstrate that it uses the Jefferson location to "secure controlled substances" and makes distributions out of its Shreveport facility. RD, at 156 (citing RX 1, at 15, 16).

Administrator that [it] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). "'Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 463 (2009) (quoting *Medicine Shoppe*, 73 Fed. Reg. 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. at 23,853; *John H. Kennnedy*, M.D., 71 Fed. Reg. 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016).

A. Acceptance of Responsibility

1. Standing and Authority to Accept Responsibility

Respondent contends that it has unequivocally accepted responsibility for the proven misconduct and that Irelan, as its Controlled Substance Compliance Officer, was both authorized by Respondent and an appropriate person to accept responsibility on behalf of Respondent. Resp Exceptions, at 8. The Agency agrees that neither Agency regulations nor prior Agency decisions clearly preclude Irelan from accepting responsibility on behalf of Respondent and will therefore

consider his acceptance of responsibility on its merits. Further, the Agency finds that the record supports that Mr. Irelan is responsible for preventing the reoccurrence of Respondent's compliance failures and accepts that Irelan obtained authority from Respondent to accept responsibility at the hearing. *See* Tr. 803 (Irelan is responsible for continued remedial measures), Tr. 1072-74[82]; *but see* Tr. 804 (decisions also go through the chain of command and to the Board).

Ultimately, as explained above, the Agency has long stated that when the Government has presented a *prima facie* case, the burden shifts to the respondent to demonstrate why it can still be entrusted with a registration in spite of its misconduct and the Agency has emphatically emphasized the requirement that respondent unequivocally accept responsibility to establish that trust. *See, e.g., Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,972 (2019); *see also Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988) (describing revocation as a remedial measure "based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration"). For several reasons, Irelan's testimony has not adequately convinced the Agency that Respondent unequivocally accepts responsibility for its past misconduct.

2. Minimization and Characterization of the Misconduct

Here, Irelan accepted responsibility for Respondent failing to effectively apply its customer due diligence in assessing orders of controlled substances, Tr. 722-23, for Respondent

[82] The ALJ did not admit RX 54; however, the Agency accepts that Irelan had authority to make compliance decisions and speak for Respondent in the proceeding.

failing to implement and maintain a suspicious order monitoring system "consistent with best practices for compliance," Tr. 729, 731,[83] and for the fact that "[t]he reporting that was being done, there were three suspicious order reports to the DEA, and that was insufficient," Tr. 731, 733. Irelan also testified that he accepted responsibility for Respondent shipping orders of controlled substances from January 2014 to May 2018 without resolving red flags and testified that he is responsible "for preventing reoccurrence of the company's past failures with respect to application of customer due diligence." Tr. 807, 721.[84]

In discussing his acceptance of responsibility for Respondent's failure to apply its customer due diligence, Irelan specifically testified that, based on his review of Respondent's records before May 2018, Respondent conducted "a tremendous amount of due diligence" on its customers. Tr. 704-05, 710. Irelan caveated that Respondent did not keep the due diligence documentation "in such a way as to make it . . . easily accessible." Tr. 705 (referring to "notes on paper," "notes . . . kept in a database" and "limited notes in our enhanced customer profile"). Nonetheless, the Agency finds that Irelan's statements claiming a "tremendous amount of due diligence" were aimed at minimizing the extent of Respondent's misconduct, which the Agency has previously weighed against a finding of unequivocal acceptance of responsibility. *See Ronald Lynch, M.D.*, 75 Fed. Reg. 78,745, 78,754 (2010) (finding that Respondent did not accept

[83] *Compare* Tr. 731 (Respondent's counsel asked whether the SOM system "was consistent with best practices *and* compliance" (emphasis added)). Whether or not this distinction from the previous statement was an error of speech, the Agency finds this statement to not differ significantly from the previous statement—in both, there was clearly a purposeful avoidance of taking responsibility for the full scope of Respondent's actions and an attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements.

[84] When Government Counsel asked him whether he accepted responsibility in several specific paragraphs of the OSC, Irelan either refused or testified that he was not in a position to answer. *See* RD, at 86. For a few of the paragraphs, Irelan's reservations seemed to be that Respondent conducted at least some additional due diligence on some of the eight pharmacies, but Irelan admitted that the due diligence was not properly applied. *See, e.g.*, Tr. 832-33, 828-29. Given the contested nature of this part of the hearing, the Agency does not find these failures to accept responsibility to imply that Irelan has not accepted responsibility for the misconduct. *See* Resp Exceptions, at 24 (arguing that these were not proven allegations). However, the Agency does find, as explained herein, that Irelan's continual insistence on referring to all of the due diligence that Respondent was conducting—while not documenting it in a retrievable manner nor applying it to the orders—was clearly intended to minimize Respondent's misconduct.

responsibility after noting that he "repeatedly attempted to minimize his [egregious] misconduct"; *see also Michael White, M.D.*, 79 Fed. Reg. 62,957, 62,967 (2014)). Additionally, Irelan's insistence that Respondent was conducting this "tremendous amount" of due diligence "but it was not applied at the order level," *e.g.*, Tr. 828, not only minimizes the violation but fails to acknowledge its scope. At the end of the day, the fact that Respondent was not *applying* the due diligence to the orders (investigating/stopping/reporting) is possibly the most impactful aspect of Respondent's violation. If Respondent was conducting due diligence that was not documented or could not be retrieved such that it could be applied to the actual filling of orders, then Respondent was not exercising effective controls against diversion because employees filling future orders would not know if there were customer-level red flags or whether they were resolved.

Further, Irelan's statements regarding whether Respondent's monitoring systems were "consistent with best practices" also clearly minimized the scope of Respondent's misconduct and did not demonstrate a full grasp of the breadth of the misconduct alleged—which was that Respondent had violated DEA regulations,[85] not failed to implement "best practices." Respondent's attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements both minimizes the severity of the violations and also demonstrates a failure to grasp of the significance of the requirements.

3. Scope of the Misconduct

The requisite acceptance of responsibility hinges on the respondent demonstrating an understanding both of the past misconduct and its extent. *See Jones*, 881 F.3d at 833. Here, the

[85] Even if Respondent chose its language to avoid drawing legal conclusions, the use of the term "best practices" was not sufficient to accurately describe the violations found herein and was clearly aimed at minimizing them. *See supra* n.83.

ALJ found that Irelan did not "acknowledge the *scope* of the Respondent's misconduct," and therefore, his acceptance was equivocal. RD, at 151 (citing *Arvinder Singh, M.D.*, 81 Fed. Reg. at 8250-51).

As Respondent stated in its Exceptions:

> Multiple United States Courts of Appeal have upheld DEA's acceptance of responsibility requirement as rational on the grounds that if a respondent "does not understand the extent of the past misconduct or its current responsibilities under the law, the DEA rationally could doubt that the [respondent] would faithfully comply in the future with its obligations under the CSA." *Jones Total Health Care Pharmacy, LLC v. [Drug Enf't Admin.]*, 881 F.3d 823, 833 (11th Cir. 2018); *accord MacKay v. [Drug Enf't Admin.]*, 664 F.3d 808, 820 (10th Cir. 2011) (admittance of fault is relevant to Administrator's consideration of whether a respondent will change its future behavior). As Respondent's current Compliance Director, Mr. Irelan has assessed Respondent's past controlled substance compliance failures and is responsible for preventing their reoccurrence.

Resp Exceptions, at 13.

In contrast to Respondent's final statement above, there were a few times where Irelan's limited involvement and knowledge of the misconduct indisputably impeded his ability to accept full responsibility, such as when, regarding Wellness Pharmacy, he was unable to state what due diligence "specifically was performed for that account." Tr. 831. The Agency finds that Irelan's admission that he had not familiarized himself with the specific due diligence performed by Respondent for the exemplar pharmacies demonstrates that he did not actually have the knowledge required to accept unequivocal responsibility on behalf of Respondent for the full extent of the violations found. Irelan's assertion that Respondent did conduct a "tremendous amount" of due diligence is also inconsistent with his stated lack of knowledge regarding the amount of due diligence conducted for the limited number of customers included in the OSC's allegations. It seems logical that in cultivating an understanding of Respondent's violations in order to adequately accept responsibility, Irelan would have focused his review on the customers

most relevant to the allegations. Therefore, Irelan does not seem to have been equipped to meet Respondent's burden in accepting responsibility.

4. Trust in Respondent

Although the Agency does not challenge Irelan's authority to act on behalf of Respondent in accepting responsibility, the burden is on *Respondent* to credibly and candidly demonstrate that it can be entrusted with a registration. Respondent chose to meet that burden by presenting Irelan's testimony in lieu of a principal or an individual who had knowledge of the full scope of the violations. Although the Agency does not contest that Respondent *could* choose Irelan to accept responsibility on its behalf, that finding does not mean that Irelan was equipped to do so unequivocally.

It is noted that the Agency has long held that the misconduct of an entity's principal is properly considered in determining whether to revoke the entity's registration. *Chip RX, L.L.C., d/b/a City Ctr. Pharmacy*, 82 Fed. Reg. 51,433, 51,438 (2017) (citing *G & O Pharmacy of Paducah*, 68 Fed. Reg. 43,752, 43,753 (2003)). An essential element of Respondent's showing of trust is that the registrant and its principals accept responsibility for their misconduct by acknowledging their wrongdoing. *Sun & Lake Pharmacy,* 76 Fed. Reg. 24,533 (citing *Medicine Shoppe*, 73 Fed. Reg. at 387; *Jackson*, 72 Fed. Reg. at 23,853; *Kennedy*, 71 Fed. Reg. at 35,709). In this case, at least one of Respondent's principals, Paul Dickson, Sr., bears at least some responsibility for the misconduct, and Irelan bears none. *See* Tr. 723.

Irelan opined that C.G. and Jacob Dickson, who were in charge of compliance during the relevant time period, were responsible for Respondent's misconduct, but was not sure enough of the "dynamics" or "reporting process" to opine about whether Paul Dickson, Sr., carried any responsibility. Tr. 808-09. The extent of the misconduct is an important factor in the Agency's

ability to determine whether to entrust Respondent with a registration and Irelan's inability to testify to the level of involvement and knowledge of Respondent's principals in the misconduct demonstrates another reason why the Agency cannot deem his acceptance of responsibility to be adequate such that the Agency can entrust Respondent with a registration. In fact, Respondent's submitted evidence includes testimony from the Hearing on the Motion for Temporary Restraining Order[86] in which Paul Dickson, Respondent's president, testified that he was primarily responsible for development of Respondent's SOM program and that he designed the system. RX 1, at 33. Paul Dickson further told the Court that in designing the system, he knew that he "didn't do a perfect job," but that "it was the best that [he] could do. And [he] think[s] it's dang good. And [he doesn't] think a single person has gotten hurt by [their] drugs. [He] sure do[esn't] know of one . . . . So [he] think[s] it works." RX 1, at 57. These statements from the president of a family-owned and -operated company so strongly miss the point of the requirements of a DEA registrant that they further undercut the Agency's ability to entrust Respondent with a registration. To equate a registrant's compliance with an agency's closed regulatory system with the consequence of knowing whether anyone was hurt "by [their] drugs" exhibits a stark misunderstanding of the regulatory requirement.

The Agency finds that Irelan's inability to describe Paul Dickson's involvement in the proven misconduct further demonstrates the inadequacy of Respondent's acceptance of responsibility in this proceeding. In all, Irelan's lack of understanding and recognition of the full

[86] It is noted that the ALJ excluded pages 147 to 216 of this transcript as irrelevant, but allowed pages 1 through 146 because Respondent offered it as remedial, mitigation, or community impact evidence. ALJX 59, at 6 (citing ALJX 29, at 2, 4.) Although it is also noted that the hearing in which these statements were made was related to the public interest in the context of the ISO, the ALJ found, and the Agency agrees, that this evidence bears some relevance to the current inquiry. *Id.* Furthermore, Respondent argues in its Exceptions that "[t]his testimony is relevant evidence of Respondent's credibility and good faith intent in working with DEA to stop diversion." Resp Exceptions, at 31. For the reasons stated above, the Agency finds that, if anything, Paul Dickson's remarks seem indignant that DEA is pursuing enforcement, seem aimed at minimizing the misconduct, and display a lack of understanding and respect for the regulatory requirements.

scope of the misconduct and attempts to minimize the misconduct lead the Agency to conclude that Respondent's acceptance of responsibility was equivocal and insufficient to ensure that Respondent can be entrusted with a registration.

B. Remedial Measures

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency has stated that it need not address the registrant's remedial measures. *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,810 (2015); *see also Ajay S. Ahuja, M.D.*, 84 Fed. Reg. at 5498 n.33; *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,202; *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,510 (2014). A registrant does not unequivocally accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195*, 77 Fed. Reg. 62,316, 62,346 (2012). Refusal to acknowledge the *full scope of misconduct*, even with remedial measures, is a risk to the public interest. *Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8250-51 (2016) (emphasis added).

The ALJ characterized Respondent's remedial measures as "impressive." RD, at 152. The Agency similarly credits the efforts that the record reflects Respondent undertook to improve its compliance with DEA's requirements after being served with the OSC. As the ALJ appropriately stated, the Agency has also made it abundantly clear that remediation alone is not adequate to avoid a sanction and that limited-to-no-weight is given to remedial measures when the effort is not made until after enforcement begins. *See Mireille Lalanne, M.D.*, 78 Fed. Reg. 47,750, 47,777 (2013) (quoting *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48,887, 48,897 (2011) ("The Agency has recognized that a cessation of illegal behavior only when 'DEA comes knocking at one's door,' can be afforded a diminished weight borne of its own opportunistic timing.")); *see also Southwood Pharm. Inc.*, 72 Fed. Reg. at 36,503 (giving no weight to

respondent's "stroke-of-midnight decision" to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer).[87]

Additionally, the ALJ found that, based on prior Agency decisions, he could give no weight to Respondent's remedial measures given the lack of Respondent's unequivocal acceptance of responsibility. RD, at 152.[88, 89] As the Agency has consistently held, "past performance is the best predictor of future performance." *Lesly Pompy, M.D.*, 84 Fed. Reg.

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[87] In its Exceptions, Respondent points to the factual distinctions between cited cases in the RD and the circumstances in this case and also points to numerous other settled cases that, in Respondent's opinion, demonstrate that the sanction here is unfair. Resp Exceptions, at 25 and 33. However, "the issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent," and it is the respondent's burden to bear. *See, e.g., Stein,* 84 Fed. Reg. at 46,972. And contrary to Respondent's arguments, the proposed sanction is supported by similar sanctions in other recent distributor adjudications where the Agency similarly found that respondents' registrations were inconsistent with the public interest and that those respondents had not demonstrated that they could be entrusted with a registration. *See Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,487 (rejecting the ALJ's sanction because it was "insufficient to protect the public interest. While [the Agency is] mindful of the corrective measures engaged in by Respondent, its sales of extraordinary quantities of controlled substances to entities which it had reason to know were diverting the drugs caused extraordinary harm to public health and safety."); *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,501.

[88] Respondent repeatedly asserts that these adjudications are difficult to defend due to what it claims is an unfair system—that Respondent must accept responsibility prior to knowing what misconduct has been proven. Resp Exceptions, at 7. Respondent chose litigation strategies presumably based on the longstanding structure and content of Agency decisions in these adjudications and the Agency does not fault it for those decisions. In the end, Respondent had the burden to prove that it could be entrusted with a registration and it has failed to meet that burden. *See Masters Pharm., Inc.*, 861 F.3d 206 (D.C. Cir. 2017) (rejecting arguments that DEA's structure of requiring acceptance of responsibility is unfair, because "under longstanding DEA precedent, once DEA presents enough evidence at hearing to show that a registered vendor or distributor of controlled substances has 'committed acts inconsistent with the public interest,' the 'registrant must present[] . . . mitigating evidence' including evidence that it has 'accept[ed] responsibility for its actions and demonstrate[d] that it will not engage in future misconduct'" (quoting *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008)). Furthermore, the Agency's finding on this issue does not hinge on whether Irelan has accepted responsibility for each proven allegation, but instead hinges on Irelan's persistent minimization of the misconduct and further on Respondent's overall failure to demonstrate that *Respondent* has *unequivocally* accepted responsibility and can be trusted with a registration.

[89] Respondent argues that Milione's testimony regarding the August 2016 meeting with Paul Dickson, Sr., *supra* n.8, demonstrates Respondent's "good faith and sincerity, which flatly contradict the ALJ's intent-laden description of Respondent's compliance as 'cavalier'" and argues that this fact is relevant in considering Respondent's likelihood towards recidivism. Resp Exceptions, at 30 (citing RD, at 156). The Agency cannot give this meeting or Paul Dickson's sincerity during this moment in time the weight that Respondent requests it be afforded given that the evidence demonstrates that for approximately two years prior to this meeting and two years afterwards, Respondent was not complying with DEA regulations. Further, Respondent did not present the Agency with Paul Dickson's testimony at this hearing to be able to weigh his credibility and sincerity either in 2016, when this meeting occurred, or at the time of the hearing. The transcribed testimony that Respondent did submit from Paul Dickson demonstrated that he believed his SOM system to be "dang good"—a statement with which the Agency emphatically disagrees. *See* RX 1, at 57.

57,749, 57,761 (2019); *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 833 (11th Cir. 2018) (affirming refusal to consider remedial measures where registrant did not accept responsibility for its misconduct); *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, 789 F. App'x 724, 2019 WL 4565481, at *7–8 (11th Cir. Sept. 20, 2019) (same).[90]

In this case, even if the Agency gave weight to Respondent's remedial measures, the measures are outweighed by the fact that it has not adequately established that Respondent as an entity fully understands the scope of the misconduct such that it can be entrusted with regulatory compliance in the future.

C. The Extent of the Misconduct

The record demonstrates that Respondent's violations of the law were not isolated occurrences, but took place over the course of four years and involved multiple customers. *See Garrett Howard Smith, M.D.*, 83 Fed. Reg. at 18,910 (collecting cases) ("The egregiousness and extent of [the] misconduct are significant factors in determining the appropriate sanction."). In spite of its self-described status as a privately-owned company that has been in business for 177 years,[91] Respondent maintained sparse documentation of its SOM procedures generally and maintained very little documentation of its resolution of red flags of diversion displayed by its customers or of individual suspicious orders. The record evidence demonstrates that Respondent attended two conferences, held a personal meeting with DEA, and received multiple letters in

[90] *See also Hills Pharmacy, LLC*, 81 Fed. Reg. 49,815, 49,847 (2016) ("[T]here is no need to consider Respondent's remedial efforts as they are rendered irrelevant by its failure to acknowledge its misconduct."); *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,810 (2015) ("[S]ince the Respondent has not tendered an unequivocal acceptance of responsibility, under established Agency precedent, [it] is foreclosed from a favorable result in these proceedings and the issue of remedial actions is irrelevant.").

[91] *See also* RX 1, at 21 (estimating Respondent's number of retail pharmacy customers at "approximately 600 primary . . . and another 200 secondary that fluctuates") and 22-23 ("[O]nly competition are what's called 'the big three,' the global companies").

which DEA emphasized the critical importance of a distributor's role in preventing diversion given the opioid crisis in the nation and reminded distributors of their obligations under the law. A letter from DEA dated September 27, 2006, stated "[G]iven the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." GX 3, at 2. In spite of Respondent's established knowledge regarding the criticality of its role in preventing "dangerous and potentially lethal consequences," Respondent did not adequately resolve or document investigation into the numerous red flags indicating diversion that its own Pro Compliance Reports identified on the exemplar pharmacies and failed to report a multitude of suspicious orders to DEA.

D. Deterrence

Finally, both specific and general deterrence strongly weigh in favor of revoking Respondent's registration. *See Daniel A. Glick, D.D.S.*, 80 Fed. Reg. at 74,810. The record demonstrates that Respondent violated DEA regulations over a lengthy time period—failing to report a multitude of suspicious orders to DEA and depriving DEA of valuable information about pharmacies and practitioners who might have been engaging in diversion or violating their obligations as DEA registrants, thus contributing to the country's devastating prescription drug abuse problem. Under these circumstances and on this record, a sanction less than revocation[92]

[92] Respondent argues without support that a sanction short of revocation would serve the same deterrence goals and would prevent harm to the community that would result from closing Respondent. Resp Exceptions, at 28, 31. The Agency does not consider community impact in its decisions. *See infra* n.96. As Respondent notes, it is difficult to know what level of sanction would deter future non-compliance in the registrant community, but in Respondent's case, where the violations were blatant, long-term, and impactful, the Agency finds, given the record before it, that revocation offers an appropriate deterrent effect. Furthermore, again, Respondent has not adequately established trust, *see supra* Section V.A.4, which is crucial to demonstrate the appropriateness of a sanction less than revocation under the Agency's consideration of specific deterrence. Respondent also argues that the ALJ erred in its deterrence analysis by failing to consider the Government's purported unwillingness to engage Respondent in settlement negotiations. Resp Exceptions, at 33-35. While a settlement agreement between the Government and a respondent

would send a message to the current and prospective registrant community that compliance with DEA regulations is not a condition precedent to maintaining a DEA registration and that a distributor can spend years insufficiently reporting suspicious orders and inadequately resolving red flags presented by its customers, so long as it finally invests in the procedures it should have had in place all along after it is caught and faces potential consequences.[93]

Although Respondent has implemented remedial measures, it has not adequately demonstrated that its leadership can be entrusted to continue these measures and prevent reoccurrence of what happened prior to the issuance of the OSC, which amounted to a SOM system that was not designed or operated in a way that would adequately prevent diversion of controlled substances nor provide DEA with information critical to its mission. Respondent argues that the ALJ erred in finding that "the continued registration of a fully remediated registrant with an 'impressive' anti-diversion regime, along with evidence of good faith desire to prevent diversion, does not serve the public interest."[94] Resp Exceptions, at 1. However, Respondent's argument neglects to mention that remediation is irrelevant without continued trust. Respondent wants credit for "commission[ing] former top DEA officials to design their

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may be a way to provide enforceable assurances of the respondent's future compliance, the parties have not reached such a settlement here. Accordingly, and although the Agency has considered alternative sanctions as Respondent has requested, it has decided that revocation currently is the most appropriate sanction as explained herein.

[93] DEA decisions have demonstrated concern that giving weight to last minute remedial measures would show the regulated community that a registrant "can unlawfully distribute controlled substances until [it] gets caught, and as long as [it] then acknowledges wrongdoing and puts on evidence that [it] has reformed, [it] will get a slap on the wrist." *David Ruben, M.D.*, 78 Fed. Reg. 38,363, 38,387 (2013); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,504 (2007) ("A precedent which ignores how irresponsibly a registrant has acted and allows it to maintain its registration based on its claim of having reformed its business practices, could well prompt other registrants to ignore their obligations under the Act and sell massive quantities of controlled substances to diverters.").

[94] Respondent argues that its "current conduct is the best evidence that its continued registration is consistent with the public interest." Resp Exceptions, at 7. However, remediation is notably not an enumerated public interest factor under 21 U.S.C. § 823(b). Remediation is a factor that the Administrator considers in reviewing the extent to which sanctions are appropriate and only after the Government has made a *prima facie* case demonstrating that the allegations support a finding that Respondent's continued registration is not in the public interest. *See, e.g., Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. at 23,853.

ideal anti-diversion system," *id.*, because it believes that as long as it has invested the money now, it will prevent DEA from enforcing against it. There are several considerations other than remediation that the Agency uses in determining sanction as explained herein. The fact is that, under these circumstances and on this record, Respondent has not adequately convinced the Agency that it can be entrusted with a registration—its acceptance of responsibility did not prove that it or its principals understand the full extent of their wrongdoing, the effect that it had on the Agency and the American public, and the potential harm that it caused.[95] It was Respondent's burden to prove that it could be entrusted to protect the public interest in maintaining a DEA registration—and it has failed to do so.

Having reviewed the record in its entirety, the Agency finds that Respondent cannot be entrusted with a DEA registration and orders that its registration be revoked. The Agency addresses collateral matters and additional issues raised in Respondent's Exceptions before issuing a final Order.

VI. Motion to Reopen

On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. Respondent seeks to introduce evidence of post-hearing conduct that it argues demonstrates

[95] Respondent attached to its Exceptions the Department of Justice Office of the Inspector General (OIG) September 2019 Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids—claiming that the report is DEA's motivation for pursuing "the harshest sanction" against Respondent. The report is dated September 2019—a month after the ALJ's issuance of the RD. Furthermore, DEA subpoenaed Respondent as early as February 1, 2018; therefore, temporally, the OIG's findings could not have motivated the Agency's investigation into Respondent. Such allegations are a distraction from the issue at hand—Respondent failed to comply with its regulatory obligations and neither the Agency nor the country could possibly have the ability to know what might have happened had those suspicious orders been reported to DEA and to what extent diversion and abuse might have been prevented. What the Agency does know is that Respondent's failures were monumental, and Respondent clearly misses the point in arguing that "had the Respondent more consistently reported suspicious orders with the DEA, it has been established that the reports would have been ignored." Resp Exceptions, at 5.

acceptance of responsibility and successful remediation.[96] Although not specifically contemplated in the CSA or regulations, DEA decisions have repeatedly held that the Administrator may, in her discretion, order that the administrative record be reopened. The party moving to reopen, however, bears a heavy burden. *See INS v. Abudu*, 485 U.S. 94, 110 (1988); *see also Cities of Campbell v. FERC*, 770 F.2d 1180, 1191 (D.C. Cir. 1985) ("Reopening an evidentiary hearing is a matter of agency discretion and is reserved for extraordinary circumstances." (citations omitted)); *Nance v. EPA*, 645 F.2d 701, 717 (9th Cir. 1981).

The Agency finds that Respondent has not met its burden to reopen the record. In all DEA administrative proceedings, there is inevitably at least some delay between the hearing and the final decision of the Administrator.[97] Allowing parties to reopen the record to introduce evidence of acceptance of responsibility and remedial measures taken during that delay would create a recursive loop further delaying the conclusion of proceedings to the detriment of the public interest. *See, e.g., Abudu*, 485 U.S. at 107; *Qoku v. Gonzales*, 156 F. App'x. 703, 705 (5th Cir. 2005). As the Supreme Court observed in *Vermont Yankee Nuclear Power Corp. v. NRDC*, "[a]dministrative consideration of evidence . . . always creates a gap between the time the record

[96] Respondent also requests to reopen the record to introduce evidence of the impact revoking its registration would have on the community. Motion to Reopen, at 20-22. The Agency has consistently found that community impact is not a relevant consideration under the public interest factors. *E.g., Stephen E. Owusu*, D.P.M., 87 Fed. Reg. 3343, 3351 n.21 (2022); *George Pursley, M.D.*, 85 Fed. Reg. 80,162, 80,188 n. 82 (2020); *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45,229, 45,239 (2020). Accordingly, Respondent's community impact evidence is not grounds to reopen the record. Further, Respondent made arguments that it should be allowed to introduce evidence that it concedes is not an independent basis to reopen the record but argues is properly admitted if the record is reopened. Reply ISO Motion to Reopen, at 12. Nonetheless, the Agency is not reaching a finding on the admissibility of this evidence because it is not granting Respondent's Motion to Reopen.

[97] The delay between the hearing and the issuance of the final decision in this matter was longer than is typical for the Agency, but the proceedings were delayed partially at Respondent's request. On March 9, 2020, Respondent wrote a letter to the then-Acting Administrator asking that the Agency postpone issuing a Final Order "to allow the COVID-19 crisis to abate or the parties to reach a final settlement . . . ." *See* Letter from Respondent. Respondent then requested yet another delay in its Motion to Reopen asking that the Administrator delay the issuance of a final order "until after [Respondent's] new counsel has had an opportunity to resolve the matter with DEA's Chief Counsel." Motion to Reopen, at 4, n.4. Respondent cannot request to delay the proceedings and then claim that a failure to reopen the record is somehow prejudicial to Respondent because of its requested delay.

is closed and the time the administrative decision is promulgated . . . . If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening." 435 U.S. 519, 554-55 (1978) (quoting *ICC v. Jersey City*, 322 U.S. 503, 514 (1944) (citing *Northern Lines Merger Cases*, 396 U.S. 491, 521 (1970)).

Respondent had the opportunity to, and did, introduce evidence related to its acceptance of responsibility and remedial measures at the hearing. That evidence was entered into the record and considered in the ALJ's Recommended Decision and this Final Order.

VII. *Lucia*

The Agency has carefully considered Respondent's Exceptions to the Recommended Decision, has addressed them throughout the record, and addresses the remaining herein.

In its Exceptions, Respondent notes that "as [it] has repeatedly and consistently objected, including at the hearing, this entire proceeding was unconstitutional." (citing Tr. 20:23-22:17). Respondent contends that "[t]he presiding ALJ in this matter was unconstitutionally appointed when these proceedings began and unconstitutionally continued to preside over these proceedings after the Attorney General purportedly ratified his appointment." (citing *Lucia v. Securities and Exchange Comm'n*, 138 S. Ct. 2044, 2055 (2018) (hereinafter, *Lucia*)). The Agency will note the factual sequence of events surrounding Respondent's *Lucia* claims.

Respondent's Prehearing Statement, filed on August 3, 2018, averred, "Respondent may file a motion before this Tribunal related to the constitutionality of the DEA's administrative process given the U.S. Supreme Court's recent decision in [*Lucia*]." ALJX 8, at 37. During the Prehearing Conference, Respondent's attorney stated, "with regards to the *Lucia* case, this is

obviously no disrespect intended to the Court but we do think that it's a significant issue that should we proceed to hearing, we do want to address and I would like to file a motion about it." The ALJ replied, "Well, if you're going to file a motion about it, I obviously would need to take a look at it . . . . Apparently, if you file a motion, there's a good chance you'll wind up with a different Judge . . . . I'm just putting you on notice that that's what's likely to happen." Prehearing, Tr. 36. The ALJ ordered that "[y]ou obviously can file motions tomorrow if you want to but any motions I'm going to need to rule on I would like to have no later than October 23rd. . . ." Tr. 42-43.

On October 26, 2018, Respondent submitted a letter on the record alerting the Tribunal that it had commenced an action in the United States District Court for the Western District of Louisiana seeking an "injunction enjoining DEA and DOJ from requiring Morris & Dickson to appear in any administrative proceeding, including the upcoming hearing scheduled for November 13, 2018, unless and until a constitutionally valid administrative system has been established." ALJX 26, at 1. On October 31, 2018, Respondent filed another letter with the Tribunal explaining that it did not file a motion with the ALJ because the Agency "has no authority to entertain a facial constitutional challenge" and that "[t]he Louisiana Court will resolve that question. Morris & Dickson simply provides this Tribunal notice of that filing and requests sufficient time to allow the Louisiana Court (and, if necessary, the Fifth Circuit Court of Appeals) to make its ruling." ALJX 34, at 1-2.

On December 31, 2018, Respondent submitted a letter notifying the Tribunal that "[o]n December 28, 2018, the District Court in the Western District of Louisiana dismissed Respondent's complaint without prejudice, finding that it did not have jurisdiction to hear Morris & Dickson's claims" and attaching the decision. ALJX 47, at 1. The Decision stated that,

although Respondent's argument was "somewhat close," "in light of the policy problem created by crafting a 'constitutional claim' exception to Congress's ability to channel initial review through agencies, the Court finds that Morris & Dickson's separation-of-powers claims are not 'wholly collateral' to the proceeding before Judge Dorman because they were raised in an attempt to delay or defeat administrative enforcement of the CSA." *Id.* at 30.

On January 15, 2019, the ALJ issued an Order Lifting the Stay and Third Prehearing Ruling. ALJX 51. The Order stated that Respondent indicated during a telephonic conference on the previous day that it "w[ould] not seek to maintain the stay in this case pending its appeal to the United States Court of Appeals for the Fifth Circuit"[98] and that "it w[ould] not file a motion seeking to recuse [the ALJ] from this case based on the Supreme Court's decision in *Lucia* . . . ." *Id.* at 1.

The next time Respondent raised the *Lucia* issue was at the beginning of the hearing on May 13, 2019. Respondent's lawyer made a self-described "statement of the record, simply," Tr. 23, that "we respectfully renew for the record our objection to the hearing and proceeding." Tr. 22. However, Respondent's lawyer also agreed that Respondent was ready to go to hearing that day and made no further motions or requests for a new ALJ. Tr. 24.

On October 25, 2018, the Attorney General ratified the prior appointment of the DEA ALJs, including ALJ Dorman, and "approved their appointments as his own under the Constitution." *See* Office of the Attorney General, Order No. 4.315-2018.[99] It is noted that, at the time that the hearing took place in this matter, ALJ Dorman's appointment as an Administrative Law Judge had been ratified. Respondent never formally requested reassignment

[98] Respondent's appeal to the United States Court of Appeals for the Fifth Circuit was dismissed by its own motion. *See Morris and Dickson v. William Barr, et. al.*, No. 19-30043, 2019 WL 3230978 (5th Cir. Apr. 1, 2019).
[99] Although not considered material to this Decision, a copy of this Order will be included in the administrative record for future reference.

nor availed itself of the opportunity to request interlocutory review to the Administrator on any ruling of the ALJ or any *Lucia*-related issue pursuant to 21 C.F.R. § 1316.62. Had Respondent contested the matter formally with the Agency, the Agency would have assigned another ALJ, *see* Prehearing, Tr. 36, and saved significant Agency resources. The Agency further finds that ALJ Dorman's appointment was ratified before the hearing. Due to Respondent's calculated choice to preserve the matter for the record, Tr. 23, but not raise it in any way that the Agency might have had the capacity to address and remedy itself, the Agency considers the argument waived for purposes of finalizing this adjudication.

Having found that Respondent cannot be entrusted with a DEA registration, the Agency issues the following Order revoking Respondent's DEA registrations.

ORDER

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a)(4) and 21 U.S.C. § 823(b), (e), I hereby revoke DEA Certificates of Registration Nos. RM0314790 and RM0335732 issued to Morris & Dickson, Co., LLC. Further, pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a)(4) and 21 U.S.C. § 823(b), (e), I hereby deny any pending application of Morris & Dickson, Co., LLC to renew or modify these registrations, as well as any other pending application of Morris & Dickson, Co., LLC. This Order is effective **[insert Date Thirty Days From the Date of Publication in the Federal Register].**

Date: MAY 19 2023

Anne Milgram
Administrator

BILLING CODE: 4410-09-P

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Docket No. 18-31
MORRIS & DICKSON CO., LLC
ORDER

On May 19, 2023, I issued and served on the parties a Decision and Order (the Decision and Order) revoking, effective 30 days from the date of publication in the Federal Register, Certificate of Registration Nos. RM0314790 and RM0335732 issued to Morris & Dickson, Co., LLC (Respondent). By motion dated May 20, 2023, Respondent requested a stay of the Decision and Order. On May 21, I issued an order soliciting additional information from Respondent and asking the Government to respond to Respondent's Motion for Stay. On May 22, both parties responded. Respondent clarified that it was requesting a stay of at least 90-to-120 days so that it can renew settlement negotiations with the Government. Respondent's May 22, 2023 Letter re Motion for Stay, at 1. Respondent also stated that a stay was necessary to mitigate the impact on its "customers, employees, and other stakeholders," including pharmacies, hospitals, and patients. *Id.* at 4-5. The Government indicated that it opposed any stay request, but stated that it was "open to settlement offers" and suggested it was willing to engage in settlement negotiations with Respondent. Government's Opposition to Motion to Stay, at 3.

Upon consideration of the entire record before me, the public interest—in particular, the potential need for Respondent's customers and their patients to find new suppliers given the revocation of Respondent's registrations—and the possibility for renewed settlement negotiations, I hereby order that the May 19, 2023 Decision and Order will be effective on [***insert Date Ninety Days From the Date of Publication of the May 19, 2023 Decision and Order in the Federal Register***]—ninety days from the date of the Decision and Order's

publication in the Federal Register. This change is reflected in the published Decision and Order.

It is so ordered.

Date: May 23, 2023

Anne Milgram
Administrator

M&D Exh. 1(C) - June 16, 2023 Indefinite Stay Order

United States Court of Appeals for the Fifth Circuit

No. 23-60284

MORRIS & DICKSON COMPANY, L.L.C.,

Petitioner,

versus

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review from an Order of the
Drug Enforcement Agency
Agency No. 88 Fed. Reg. 34523

UNPUBLISHED ORDER

Before HAYNES, ENGELHARDT, and OLDHAM, *Circuit Judges.*

PER CURIAM:

On the showing made, IT IS ORDERED that Petitioner's opposed motion for stay pending appeal is GRANTED.

M&D Exh. 1(D) – November 3, 2023 Abeyance Order

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

November 08, 2023

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW:

No. 23-60284 Morris & Dickson v. DEA
Agency No. 88 Fed. Reg. 34523

Enclosed is an order entered in this case.

Sincerely,

LYLE W. CAYCE, Clerk

Shea E. Pertuit

By: _____
Shea E. Pertuit, Deputy Clerk
504-310-7666

Mr. Daniel J. Aguilar
Ms. Anita J. Gay
Mr. Harry Graver
Mr. Jeffrey Johnson
Mr. Stephen Matthew Krsacok
Mr. Joshua Marc Salzman
Ms. Anna Manchester Stapleton

United States Court of Appeals for the Fifth Circuit

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Petitioner,

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DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review from an Order of the
Drug Enforcement Agency
Agency No. 88 Fed. Reg. 34523

ORDER:

IT IS ORDERED that the joint motion of the parties to stay further proceedings in this court, to facilitate settlement discussions, is GRANTED in part, in that the matter is stayed for ninety (90) days from the date this order is entered, whereupon the deadlines for filing briefs shall be reinstated with DEA's answering brief due 14 days from such date; and DENIED in all other respects.

The parties shall jointly file a status report forty-five (45) days from the date this order is entered, updating the progress of any discussions referenced in the joint motion.

KURT D. ENGELHARDT
United States Circuit Judge

CIVIL SETTLEMENT AGREEMENT

This Civil Settlement Agreement ("Civil Settlement Agreement") is entered by and between the United States Attorney's Office for the Western District of Louisiana ("USAO"), acting on behalf of the United States Department of Justice and the United States Drug Enforcement Administration ("DEA") (collectively referred to as the "United States") and Morris & Dickson Company, LLC ("Morris & Dickson") (each a "Party" and collectively the "Parties").

RECITALS

A. Morris & Dickson owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II – V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. (Controlled Substances Act or "CSA") (each a "Distribution Center" and collectively the "Distribution Centers").

B. In determining whether to register an applicant to distribute Schedule II – V controlled substances, the Attorney General, acting through the DEA, must consider the applicant's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels. 21 U.S.C. §823(b)(1) and (e)(1).

C. Section 1301.74(b) of Title 21 of the Code of Federal Regulations requires registrants to operate a system to identify suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered.

D. Morris & Dickson acknowledges that its DEA-registered distribution centers were and are required to comply with the CSA and the regulations promulgated thereunder, including the requirement described in Paragraph C.

E. The DEA, by its Administrator, has pending an Order to Show Cause for Morris & Dickson to appear and show cause why the DEA registration of Morris & Dickson should not be revoked. *See In the Matter of Morris & Dickson Co., LLC*, DEA Administrative Court Docket No. 18-31.

F. In parallel to the DEA Administrative Proceeding set forth in Paragraph E, the United States Attorney's Office for the Western District of Louisiana conducted a civil investigation with the assistance of the DEA's New Orleans Field Division into alleged failures by Morris & Dickson to inform the DEA of suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b).

G. The United States contends that Morris & Dickson failed to inform the DEA of suspicious orders as required by 21 C.F.R. §1301.74(b). The United States further contends that these violations subject Morris & Dickson to civil penalties under 21 U.S.C. §§842(a)(5) and (c)(1), as well as injunctive relief under 21 U.S.C. §843(f).

H. This Settlement Agreement is neither an admission of liability by Morris & Dickson nor a concession by the United States that its claims are not well founded.

I. To avoid the delay, expense, inconvenience, and uncertainty of litigating the above-referenced claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-I set forth above are fully adopted herein.

2. For purposes of this Agreement, "Covered Conduct" shall mean the followings:

   i. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b); and

ii. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA and DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5).

3. Morris & Dickson shall pay to the United States the total sum of TWENTY-TWO MILLION U.S. DOLLARS ($22,000,000.00) (the "Settlement Amount"), within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to Morris & Dickson by the United States Attorney's Office for the Western District of Louisiana. Failure of Morris & Dickson to pay the Settlement Amount as set forth herein will void this Agreement and, in such an event, the United States may pursue any and all available remedies against Morris & Dickson for any of the Covered Conduct herein.

4. In consideration of the undertakings by Morris & Dickson contained herein, and subject to the exceptions in Paragraph 5 below (concerning excluded claims), and conditioned upon Morris & Dickson's full payment of the Settlement Amount within the requisite time frame, the United States agrees to:

(i) Fully and finally release Morris & Dickson from any and all civil penalty claims under 21 U.S.C. § 842, as well as any and all claims for injunctive relief under 21 U.S.C. § 843, that the United States could have asserted, or may assert in the future, against Morris & Dickson related to the Covered Conduct; and

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. §842 or any action for injunctive relief under 21 U.S.C. §843 against Morris & Dickson or any of its

subsidiaries, affiliates, predecessors, successors, parent companies, and assigns of each, based on, arising from, or related to the Covered Conduct.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, the United States specifically reserves and does not release:

i. Any administrative action by the DEA based on or related to the Covered Conduct, but which does not solicit or impose civil penalties;

ii. Any federal criminal liability;

iii. Any criminal, civil or administrative claim arising under Title 26, United States Code (Internal Revenue Code);

iv. Any liability under the False Claims Act, 31 U.S.C. §3729 or the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812;

v. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and/or

vi. Any liability based on obligations created by this Agreement.

6. In consideration of the undertakings of the United States contained herein, Morris & Dickson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that Morris & Dickson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that Morris & Dickson reserves and does not release any liability based on obligations created by this Agreement. Morris & Dickson also reserves and does not release any liability based on the appointment and removal of administrative law judges under the CSA and the regulations

promulgated thereunder, unless and until such action becomes moot by the termination of the DEA Administrative Proceeding (18-31).

7. Nothing in the Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue law, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

9. Each Party shall bear its own legal or other costs incurred in connection with this matter, including the preparation, execution and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. Each Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties will be the United States District Court for the Western District of Louisiana, Shreveport Division.

12. For the purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written

Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

14. The undersigned individuals represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

15. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form or signature, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Morris & Dickson and its successors, transferees, heirs, and assigns.

17. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

18. This Agreement shall be effective (final and binding) on the date of signature by the last signatory to the Agreement (the "Effective Date" of this Agreement).

[Signatures to begin on next page]

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

DATED: May 9, 2019

Paul Dickson, CEO
Morris & Dickson Company, LLC

DATED: _____, 2019

Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By: _____

DATED: May 10, 2019

David C. Joseph
United States Attorney
Western District of Louisiana

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: _____, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: 10 May, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By:_____ DATED: _____, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

M&D Exh. 3 - AL BOP Order to Show Cause

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MORRIS & DICKSON CO, L.L.C.	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 193240	)	**CASE NO: 20-L-0013**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Morris & Dickson Co, L.L.C.
P.O. Box 51367
Shreveport, Louisiana 71135

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on August 17, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Morris & Dickson Co, L.L.C. (MDC) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that MDC has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this State based upon the DEA suspending your Controlled Substances Registration and/or the Settlement Agreement between you and the United States attached hereto as Exhibit "A", to include but not limited to, what is described as "Covered Conduct" in the referenced Settlement Agreement.

At the aforesaid time and place and from time to time thereafter as may be

directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 29th day of March, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT "A"

CIVIL SETTLEMENT AGREEMENT

This Civil Settlement Agreement ("Civil Settlement Agreement") is entered by and between the United States Attorney's Office for the Western District of Louisiana ("USAO"), acting on behalf of the United States Department of Justice and the United States Drug Enforcement Administration ("DEA") (collectively referred to as the "United States") and Morris & Dickson Company, LLC ("Morris & Dickson") (each a "Party" and collectively the "Parties").

RECITALS

A. Morris & Dickson owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II – V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. (Controlled Substances Act or "CSA") (each a "Distribution Center" and collectively the "Distribution Centers").

B. In determining whether to register an applicant to distribute Schedule II – V controlled substances, the Attorney General, acting through the DEA, must consider the applicant's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels. 21 U.S.C. §823(b)(1) and (e)(1).

C. Section 1301.74(b) of Title 21 of the Code of Federal Regulations requires registrants to operate a system to identify suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered.

D. Morris & Dickson acknowledges that its DEA-registered distribution centers were and are required to comply with the CSA and the regulations promulgated thereunder, including the requirement described in Paragraph C.

E. The DEA, by its Administrator, has pending an Order to Show Cause for Morris & Dickson to appear and show cause why the DEA registration of Morris & Dickson should not be revoked. *See In the Matter of Morris & Dickson Co., LLC*, DEA Administrative Court Docket No. 18-31.

F. In parallel to the DEA Administrative Proceeding set forth in Paragraph E, the United States Attorney's Office for the Western District of Louisiana conducted a civil investigation with the assistance of the DEA's New Orleans Field Division into alleged failures by Morris & Dickson to inform the DEA of suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b).

G. The United States contends that Morris & Dickson failed to inform the DEA of suspicious orders as required by 21 C.F.R. §1301.74(b). The United States further contends that these violations subject Morris & Dickson to civil penalties under 21 U.S.C. §§842(a)(5) and (c)(1), as well as injunctive relief under 21 U.S.C. §843(f).

H. This Settlement Agreement is neither an admission of liability by Morris & Dickson nor a concession by the United States that its claims are not well founded.

I. To avoid the delay, expense, inconvenience, and uncertainty of litigating the above-referenced claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-I set forth above are fully adopted herein.

2. For purposes of this Agreement, "Covered Conduct" shall mean the followings:

   i. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b); and

ii. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA and DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5).

3. Morris & Dickson shall pay to the United States the total sum of TWENTY-TWO MILLION U.S. DOLLARS ($22,000,000.00) (the "Settlement Amount"), within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to Morris & Dickson by the United States Attorney's Office for the Western District of Louisiana. Failure of Morris & Dickson to pay the Settlement Amount as set forth herein will void this Agreement and, in such an event, the United States may pursue any and all available remedies against Morris & Dickson for any of the Covered Conduct herein.

4. In consideration of the undertakings by Morris & Dickson contained herein, and subject to the exceptions in Paragraph 5 below (concerning excluded claims), and conditioned upon Morris & Dickson's full payment of the Settlement Amount within the requisite time frame, the United States agrees to:

(i) Fully and finally release Morris & Dickson from any and all civil penalty claims under 21 U.S.C. § 842, as well as any and all claims for injunctive relief under 21 U.S.C. § 843, that the United States could have asserted, or may assert in the future, against Morris & Dickson related to the Covered Conduct; and

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. §842 or any action for injunctive relief under 21 U.S.C. §843 against Morris & Dickson or any of its

subsidiaries, affiliates, predecessors, successors, parent companies, and assigns of each, based on, arising from, or related to the Covered Conduct.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, the United States specifically reserves and does not release:

i. Any administrative action by the DEA based on or related to the Covered Conduct, but which does not solicit or impose civil penalties;

ii. Any federal criminal liability;

iii. Any criminal, civil or administrative claim arising under Title 26, United States Code (Internal Revenue Code);

iv. Any liability under the False Claims Act, 31 U.S.C. §3729 or the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812;

v. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and/or

vi. Any liability based on obligations created by this Agreement.

6. In consideration of the undertakings of the United States contained herein, Morris & Dickson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that Morris & Dickson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that Morris & Dickson reserves and does not release any liability based on obligations created by this Agreement. Morris & Dickson also reserves and does not release any liability based on the appointment and removal of administrative law judges under the CSA and the regulations

promulgated thereunder, unless and until such action becomes moot by the termination of the DEA Administrative Proceeding (18-31).

7. Nothing in the Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue law, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

9. Each Party shall bear its own legal or other costs incurred in connection with this matter, including the preparation, execution and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. Each Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties will be the United States District Court for the Western District of Louisiana, Shreveport Division.

12. For the purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written

Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

14. The undersigned individuals represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

15. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form or signature, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Morris & Dickson and its successors, transferees, heirs, and assigns.

17. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

18. This Agreement shall be effective (final and binding) on the date of signature by the last signatory to the Agreement (the "Effective Date" of this Agreement).

[Signatures to begin on next page]

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: May 9, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: _____, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By: _____ DATED: May 10, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: _____, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: 10 May, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By:_____ DATED: _____, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

M&D Exh. 4 - Kentucky BOP Letter of Concern

ANDY BESHEAR
GOVERNOR

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

BOARD MEMBERS
JASON BELCHER, CONSUMER
PETER P. COHRON, R.PH.
MEREDITH FIGG, PHARM.D.
ANTHONY TAGAVI, PHARM.D.
JOHN FULLER, R.PH.
JONATHAN VAN LAHR, R.PH.

EXECUTIVE DIRECTOR
CHRISTOPHER P. HARLOW, PHARM D.

February 7, 2022

Morris and Dickson, LLC
10301 HWY 1 South
Shreveport, Louisiana 71115
License: W02005

RE: LETTER OF CONCERN, 18-0364

Dear Permit Holder:

At its January 19, 2022, meeting, the Board of Pharmacy's Case Review Panel, comprised of three board members, considered a grievance alleging that you entered a Settlement Agreement with the United States government to pay civil penalty claims and to invest in significant upgrades to your compliance program for allegedly violating the Controlled Substances Act by failing to report suspicious orders of hydrocodone and oxycodone by pharmacies. From the period of January 2014 through April 2018, there were eleven suspicious orders by three Kentucky pharmacies. The Panel reviewed the case report, Settlement Agreement, policies and procedures prior to the Settlement Agreement, and policies and procedures after the Settlement Agreement.

Having considered all the information available and being sufficiently advised, the Panel found that there is insufficient evidence of a violation to warrant the issuance of a Complaint, but that there is evidence of a practice or activity that requires modification. The Panel expressed concern regarding the Settlement Agreement and its relation to the suspicious orders of hydrocodone and oxycodone to three Kentucky pharmacies, which would qualify as a violation of KRS 315.121 (1)(c)2. The Panel determined that this letter of concern be issued.

Sincerely,

Peter P. Cohron
President
Kentucky Board of Pharmacy

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Novo
Address: 100 College Road West City: Princeton State: NJ Zip: 08540
Name: Janssen
Address: 1 Campus Drive City: Somerset State: NJ Zip: 08873
Name: Gilead
Address: 550 Cliffside Drive City: San Dimas State: Zip: 91773
Name: Abbvie
Address: 200 Abbott Park Road City: Abbott Park State: IL Zip: 60064

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Louisiana
Parent Company (if any): Morris & Dickson Holding Co., LLC
Corporation/Organization Name: Morris & Dickson Co., LLC
Mailing Address: P.O. Box 51367
City: Shreveport State: LA Zip: 71135
Telephone: 318-797-7900 Email: licensing@morrisdickson.com
Contact Person Name: Scott Irelan

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Morris & Dickson Co., LLC

Facility Name

Paul Dickson Jr

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/22/2023

Date

Board Use Only	Date Received: 11/28/23	Amount: $1000 Check #11180

NABP ACCREDITED
DRUG DISTRIBUTOR

Morris & Dickson Co LLC

located at

10301 Highway 1 South, Shreveport, LA 71115

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

08/07/2021 - 08/06/2024
Period of Accreditation

Morris & Dickson

Officers & Directors Addresses

Name	Information
Jody McLendon Hatcher, CEO	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Paul Meade Dickson, Jr., COO	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Clayton Rigby Dickson, Vice President	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Jeffrey Scott Irelan, Director of Compliance	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Braden Hunter, CFO	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Jason Hanks, Chief Commercial Officer	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900
Krista Tongring, Interim Chief Compliance Officer	410 Kay Lane Shreveport, LA 71115 Phone: 318-797-7900

Morris & Dickson Co., L.L.C.
P.O. Box 51367
Shreveport, LA 71135-1367
318-797-7900 phone
FEIN: 72-0266645

Share ownership

	Class B Non-Voting Shares 7,773 Total shares		Class A Voting Shares 72 Total shares		All Shares 7,845 Total shares	
Name / Entity	Number Shares	Sharing Ratio	Number Shares	Sharing Ratio	Number Shares	Sharing Ratio
Morris & Dickson Holding Co., L.L.C. FEIN: 82-4587826	7,773	100.0000%	72	100.0000%	7845	100.0000%

UNITED STATES OF AMERICA

State of Louisiana

R. Kyle Ardoin

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

MORRIS & DICKSON CO., L.L.C.

A limited liability company domiciled in SHREVEPORT, LOUISIANA,

Filed charter and qualified to do business in this State on June 20, 2003,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

March 27, 2023

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Secretary of State

Web 35503692K

Certificate ID: 11707716#DSL73

To validate this certificate, visit the following web site, go to **Business Services**, **Search for Louisiana Business Filings**, **Validate a Certificate**, then follow the instructions displayed.
www.sos.la.gov

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

SUB-TYPES: Standard Distributor, Wholesale Distributor, Third-Party Logistic Provider Distributor

MORRIS & DICKSON CO., LLC.

License No. **4299** effective **01/01/2024** *(Original issue date: 06/11/2004)*, Expiring **12/31/2024**
distributing from **10301 Highway 1 South, Shreveport, LA, 71115**
BUSINESS ADDRESS: 410 KAY LANE, SHREVEPORT, LA, 71115
is duly licensed in the State of Louisiana with this Board under the provisions of Act 852 of 1988 (as amended).
This license is subject to regulation in the state of Louisiana
in accordance with La. R.S. 37:3461 through 3482 and LAC 46:XXXIV.101 through 1503.

Additional Third-Party Logistics Providers:
NA

Board Secretary

ORIGINAL LICENSE — DISTRIBUTOR
This License is NOT TRANSFERABLE and must be Conspicuously Displayed. This license must be renewed annually.

Louisiana Board of Drug and Device Distributors 12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816	Phone: (225) 295-8567 Fax: (225) 295-8568	www.drugboard.la.gov Email: admin@drugboard.la.gov

SUB-TYPES:

Standard Distributor: Any entity that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

Wholesale Distributor: Any entity that sales or facilitates the delivery of drug product (as defined by FDA) to persons other than the consumer or patient; not to include (not limited to) manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

Third-party Logistics Provider: Any entity that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/31/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Arthur J. Gallagher Risk Management Services, LLC 470 Ashley Ridge Boulevard Shreveport LA 71106	**CONTACT NAME:** Myriam Victoria **PHONE (A/C, No, Ext):** 318-629-8125 **FAX (A/C, No):** 318-798-5507 **E-MAIL ADDRESS:** Myriam_Victoria@ajg.com
INSURED MORRIS & DICKSON CO., LLC P. O. Box 51367 Shreveport, LA 711351367	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** ACE American Insurance Company — 22667 **INSURER B :** Bridgefield Casualty Insurance Company — 10335 **INSURER C :** Everspan Indemnity Insurance Company — 16882 **INSURER D :** General Star Indemnity Company — 37362 **INSURER E :** Technology Insurance Company, Inc — 42376 **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** 114546421 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDC G47347026	9/1/2023	9/1/2024	EACH OCCURRENCE	$ 10,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			ISA H10751615	9/1/2023	9/1/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
C	☐ UMBRELLA LIAB X OCCUR			QM1EII-000239-01	9/1/2023	9/1/2024	EACH OCCURRENCE	$ 2,000,000
	X EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$ 2,000,000
	☐ DED ☐ RETENTION $						Excess Auto Only	$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			0196-58739	9/1/2023	9/1/2024	X PER STATUTE ☐ OTH-ER	
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐	N / A		19900022	9/1/2023	9/1/2024	E.L. EACH ACCIDENT	$ 1,000,000
E	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			TWC4306574	9/1/2023	9/1/2024	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
D	Excess Auto Liability			IXG677426	9/1/2023	9/1/2024	Each Occurrence Aggregate	$2,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Certificate holder is included as Additional Insured on the General Liability policy, as per endorsement # CG 20 26, Edition (04/13) and Auto Liability policy, as per endorsement #CA990187, edition (07/15).
Waiver of Subrogation applies to certificate holder, as respects to the General Liability & Auto Liability policies, pursuant to and subject to the policy's terms, definitions, conditions and exclusions.

Excess Liability is Excess of Primary Auto Liability only.

CERTIFICATE HOLDER

FOR INFORMATION ONLY

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Continuation of our Reference NUSCGS049358

COPY OF STANDBY LETTER OF CREDIT ISSUED

DATE : 01 Nov 2023

IRREVOCABLE STANDBY LETTER OF CREDIT REFERENCE NO.: NUSCGS049358

TO: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PARKWAY,
SUITE 206 RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

DEAR SIR/MADAM,

WE HEREBY ISSUE OUR IRREVOCABLE STANDBY LETTER OF CREDIT IN YOUR FAVOR.

BENEFICIARY	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PARKWAY, SUITE 206 RENO, NV 89521 ATTN: EXECUTIVE SECRETARY
ACCOUNT PARTY	:	MORRIS & DICKSON CO., L.L.C. 10301 HIGHWAY 1 SOUTH SHREVEPORT, LA, 71115
DATE OF EXPIRY	:	30-SEP-2024
PLACE OF EXPIRY	:	OUR COUNTER
AMOUNT	:	USD 25,000.00
APPLICABLE RULE	:	ISP LATEST VERSION

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF MORRIS & DICKSON CO., L.L.C., WE JPMORGAN CHASE BANK, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF USD 25,000.00 (TWENTY FIVE THOUSAND AND 00/ 100 U.S. DOLLARS) .

2. WE UNDERSTAND THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE ACCOUNT PARTY/LICENSEE.

3. WE FURTHER UNDERSTAND THAT THIS CREDIT IS INTENDED TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY ACCOUNT PARTY/ LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING ACCOUNT PARTY/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS BELOW.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE BY REGISTERED MAIL, RETURN RECEIPT REQUESTED, OR COURIER.

Continuation of our Reference NUSCGS049358

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL SEND THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFOR, AND RETURN THE DOCUMENTS TO THE BOARD.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED IN WHOLE OR IN PART ONLY UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA AND INTERNATIONAL STANDBY PRACTICES, 1998, I.C.C. PUBLICATION NO. 590 ('ISP98'). AS TO THE MATTERS NOT COVERED BY ISP98, SHALL BE SUBJECT TO LAWS OF THE STATE OF NEVADA.

PLEASE ADDRESS ALL CORRESPONDENCE REGARDING THIS STANDBY LETTER OF CREDIT QUOTING OUR REFERENCE NUSCGS049358 TO:
JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

THE STATE OF NEVADA

Continuation of our Reference NUSCGS049358

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS049358 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,

Authorized Signature
Ralph Davis
VP - Operations Manager

END OF COPY

JPMORGAN CHASE BANK, N.A.
TRADE & WORKING CAPITAL
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128
SWIFT: CHASUS33

To:
Morris & Dickson Co., L.L.C.
10301 Highway 1 South
Shreveport, Louisiana, 71115

Date: 01 Nov 2023
Subject : Acknowledgement Advice for Standby Letter of Credit
Our Reference : NUSCGS049358

Dear Sir/Madam,

Your Reference	:	NEVADA STATE
Standby LC Reference	:	NUSCGS049358
Account Party	:	Morris & Dickson Co., L.L.C. 10301 Highway 1 South Shreveport, LA, 71115
Beneficiary	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PARKWAY, SUITE 206 RENO, NV 89521 ATTN: EXECUTIVE SECRETARY

As per your request we have issued our Irrevocable Standby Letter of Credit in the favor of beneficiary under our reference number stated above.

We hereby enclose the copy of the Irrevocable Standby Letter of Credit for your information and record purpose.

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS049358 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,

Authorized Signature
Ralph Davis
VP - Operations Manager

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Morris & Dickson Co., LLC MDEG License # (if applicable): N/A

Physical Address: 10301 Highway 1 South

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 51367

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Website: www.morrisdickson.com

Licensing Company Email: licensing@morrisdickson.com

Section 2: Personal Information

First: Ryan Middle: Shane Last: Wagner

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Email: licensing@morrisdickson.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Louisiana State University - Shreveport		08/2000-12/2001	
Address	City	State	Zip
One University Place	Shreveport	LA	71115
Diploma/Degree obtained, if any			
College			

School Name		From - To (MM/YY – MM/YY)	
Southwood High School		08/1997-05/2000	
Address	City	State	Zip
9000 Walker Road	Shreveport	LA	71118
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2011- Present	[redacted]	Stonewall	LA	71078
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Morris & Dickson Co., LLC			02-2003 - Present	
Business Address		**City**	**State**	**Zip**
10301 Highway 1 South		Shreveport	LA	71115
Phone	**Title**		**Number of Employed Hours**	
318-797-7900	Assistant Inventory Control Manager		41,766.40	
Description of Duties				
Please see attached.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Ryan Wagner
Morris & Dickson
Daily Duties

- Calculate sales to ensure product location and supply is most efficient for DC flow
- Communicate with manufacturers and buyers to resolve errors pertaining to shipment or receiving errors
- Review cycle counts and resolve discrepancies while logging reports in excel spreadsheets
- Review customer reported errors in shipment shortages or overages due to human error
- Research in house credits due to shortages while also issuing customer credit to their account
- Assign new incoming product an appropriate location best for the DC flow
- Maintain inventory levels and expiration dates to ensure rotation of product by expiration date order
- Receive and store vaccine shipments
- Manage and log errors by creating reports of employee errors to improve accuracy
- Assist and lead inventory assistants for their daily tasks

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-22-23
Date

I, Ryan Shane Wagner, **certify that as the MDEG Administrator for**

Morris & Dickson Co., LLC,

that I (initial that you have read and meet the following requirements):

1. RW Have a high school diploma or its equivalent;
2. RW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Wagner
Print Name (First, Last)

Ryan Wagner
Original Signature (electronic, copies or stamps not accepted)

11-16-23
Date

Board Use Only	Date Received: 11/28/23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Morris & Dickson Co., LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 10301 Highway 1 South

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 51367

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Website: www.morrisdickson.com

Licensing Company Email: licensing@morrisdickson.com

Section 2: Personal Information

First: Ryan Middle: Shane Last: Wagner

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Email: licensing@morrisdickson.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Louisiana State University-Shreveport		08/2000-12/2001	
Address	City	State	Zip
One University Place	Shreveport	LA	71105
Diploma/Degree obtained, if any			
College			

School Name		From - To (MM/YY – MM/YY)	
Southwood High School		08/1997-05/2000	
Address	City	State	Zip
9000 Walker Road	Shreveport	LA	71118
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2011- Present	[redacted]	Stonewall	LA	71078
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Morris & Dickson Co., LLC			From - To (MM/YY – MM/YY): 02/2003 - Present
Business Address: 10301 Highway 1 South	City: Shreveport	State: LA	Zip: 71115
Phone: 318-797-7900	Title: Assistant Inventory Control Manager		Number of Employed Hours: 41,766.40
Description of Duties: Please see attached.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Ryan Wagner
Morris & Dickson
Daily Duties

- Calculate sales to ensure product location and supply is most efficient for DC flow
- Communicate with manufacturers and buyers to resolve errors pertaining to shipment or receiving errors
- Review cycle counts and resolve discrepancies while logging reports in excel spreadsheets
- Review customer reported errors in shipment shortages or overages due to human error
- Research in house credits due to shortages while also issuing customer credit to their account
- Assign new incoming product an appropriate location best for the DC flow
- Maintain inventory levels and expiration dates to ensure rotation of product by expiration date order
- Receive and store vaccine shipments
- Manage and log errors by creating reports of employee errors to improve accuracy
- Assist and lead inventory assistants for their daily tasks

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 & 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

**********Questions 5 & 6 were both answered no, as Ryan Wagner, the Designated Representative, is not associated with the business as an owner, partner, member, officer, or director. A narrative was provided by the company, and the owner, listing administrative proceedings.**********

Original Signature (electronic, copies or stamps not accepted)

11-17-23
Date

I, Ryan Shane Wagner, **certify that as the designated representative for**

Morris & Dickson Co., LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RW I am at least 21 years of age;
3. RW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ryan Wagner

Print Name (First, Last)

Ryan Wagner

Original Signature (electronic, copies or stamps not accepted)

11-16-23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Wagner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-16-23

Date

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of Caddo Parish

I, Ryan Shane Wagner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-16-23

Date

Subscribed and Sworn to before me this 16th day of November

Notary Public Signature

Shannon Moffett
Caddo Parish, Louisiana
Notary Public
Commission No. 179902
My Commission Expires Upon Death

(Seal)

Employee List

First Name	Last Name
Alan	Bass
Ashley	Burchett
Amber	Call
Aldrian	Carroll
Ananth	Darsi
Alivia	Demery
Annette	Edwards
Annie	Fuller
Angie	Gray
Alyssa	Huffman
Alfred	Jackson
Artie	Jason
Arnold	Jewitt
Alisha	Jordan
Alexandra	Shaver
Andrea	Swenson
Amante Flor Jr	Tagaban
Alisa	Vance
Amy	Walker
Amber	Walker
Andrew	Winham
Angela	Wyatt
Bis	Admin
Bis	Admin
Barrett	Atkinson
Beverly	Barr
Bobbie	Dubois
Bobby	Flores
Brandon	Floyd
Braden	Hunter
Brittany	Igo
Brian	Moseley
Beverly	Musco
Blanka	Rainko
Brenda	Sapp
Bo	Seefeldt
Bis	Test
Braylon	Thomas
Brandon	Vo
Bennie	West
Betty	Williams
Brittany	Wilson
Christopher	Call

Cindy	Cobbs
Candasis	Collins
Carolina	Contreras
Caleb	Creal
Carol	Davis
Clayton	Dickson
Christopher	Garrett
Charie	Gipa
Courtney	Graham
Clara	Guin
Christie	Hamilton
Cornelius	Hill
Christian	Jacobs
Cassandra	Johnson
Christopher	Johnson
Cynthia	Kittle
Christopher	Leon
Christopher	Logan
Carissa	Lott
Chris	Mcclain
Clifford	Nelson
Chris	Parker
Christopher	Pedeaux
Clarence	Rainbolt
Cheryl	Saucier
Cathy	Sparks
Charles	Tarver
Cherelyn	Thompson
Christian	West
Curtis	Williams
Christian	Williams
Cleotha	Williams Jr
Courtney	Willis
Donald	Allen
Dustin	Allen
David	Austin
Demarcus	Ball
Daniel	Boucher
Flayo	Cain
Don	Cain
Douglas	Claycomb
Darell	Cottonham
Dennis	Crumpton
Debra	Ely
Deshunda	Franklin
Daniel	French
Dennis	Harr

Daniel	Hoskins
Deborah	James
David	Kirby Jr
Denise	Laenger
Donald	Levi
Daniel	Lynch
Dennis	Marshall
Demarcus	Mccall
David	Mccuen
Deidra	Milczarski
Dennis	Patrick
Darlene	Ramsey-Lang
Devin	Robinson
Donald	Stewart
Danna	Stutts
Darrell	Waldon
David	Watters
Devorah	Williams
Donna	Willis
Daniel	Wood
Derick	Wray
Earnestine	Brown
Elizabeth	Collins
Eileen	Ferguson
Elijiah	Hallmon-Cox
Evelyn	Hayman
Erik	Lejeune
Erik	Marr
Eric	Shuler
Erin	Straus
Eric	Wells
Elaine	Woods
Frank	Hanson
Frederick	Smith
Gary	Anderson
Garrett	Bass
Gene	Fitzgerald
Gavin	French
Garrett	Gresham
Gregory	Guthrie
Gabjoyce	Labadlabad
Gidget	Pearson
Gina	Pouncy
Gloria	Whitehurst
Harley	Croff
Henry	Dannehl
Hugh	Herzog

Harold	Quinn
Herlandez	Roberson
Irene	Schuler
Judy	Abney
Joshua	Amato
Jaime	Barouh
Jeanie	Bruner
James	Clark
John	Crichton
Jeremy	Curtis
Jasmine	Dewitt
John	Henry Iii
Joshua	Fontenot
John	Frazier
Jaylon	Frazier
Jonathan	Gantt
Janerica	Gay
Jacquueline	Gee
Jaxon	Goodman
Justin	Gray
Jetedra	Guillory
Jean	Hall
Jason	Hanks
Jaylen	Garvin
Jody	Hatcher
Janice	Hays
Joshua	Herrick
John	Huddleston
Jonathan	Hutson
Jordyn	Jackson
Joseph	Johnson
Jacques	Jones
James	Kenney
Jocelyn	Labadlabad
James	Lester
Jason	Lilley
Jerryl	Luvisi
Jesse Kim	Magale
Jason	Mccoy
Jamie	Mckeever
Jadon	Mckeever
Jason	Montalbano
Jaden	Musco
Jeanylyn	Newman
John	Pabua
James	Parker
Jeremy	Quinn

Janice	Rice
Jimmy	Shaver
Scott	Irelan
Johnny	Thomas
Jacki	Turner
James	Washburn
Joshua	Washington
Jeffery	Whitaker
Johnathon	White
Jill	Williams
Jackie	Williams
Janet	Yearling
Jason	Zingg
Kevin	Alexander
Kyndall	Ardoin
Kelly	Best
Kevin	Blanton
Kyron	Bogan
Katina	Douglas
Kim	Green
Khrislyn	Guillory
Kiana	Harris
Kevin	Hawkey
Kirt	Heggen
Karin	Hernandez
Kevin	Hite
Kenneth	Jackson
Kimberly	King
Kris	Klaus
Kurt	Leonards
Kimberly	Lewis
Kalonda	Lewis
Katrina	Nelson
Kaylon	Nunsett
Kyron	Reed
Kristina	Sistrunk
Kenneth	Solomon
Kimberly	Temms
Kevin	Webb
Katheryn	Webster
Kristen	Williams
Kevin	Williams
Keyon	Wyatt
Loren	Brown
Lucas	Carscadden
Liddie	Cummings
Linda	Gartner

Lashanda	George
Lisa	Gill
Lasheradon	Guye
Lindsey	Hailey
Lara	Harris
Lance	Hawkins
Leona	Hawthorne
Loni	Johnson
Lorna	Lorna
Lafonya	Lewis
Lamarion	Love
Lisa	Lowery
Linda	Montgomery
Leslie	Rogers
Linda	Rogers
Lisa	Rushing
Louis	Taylor
Lance	Thompson
Lynette	Van Heerden
Llewellyn	Vanwey
Mike	Carlton
Marcos	Carrillo
Mike	Casida Ii
Milton	Choyce
Michael	Coe
Madhavi	Darsi
Miguel	Garza
Macky	Giles
Miller	Glenn
Malajah	Golatt
Michael	Gray
Mary	Green
Mona	Herrington
Miles	Iverson
Michelle	Jenkins
Michael	Jernigan
Mark	Jester
Marilyn	Johnson
Michael	Lacombe
Marian	Lester
Makaila	Lewis
Mackosha	Logan
Michael	Mcfann
Mike	Micheels
Marshall	Miller
Melissa	Moncrief
Mary Frances	Morgan

Mackenzi	Morgan
Michael	Pfender
Mona	Pomraning
Michael	Powell
Michael	Reaves
Marshawn	Satchell
Matt	Shaver
Michael	Shaw
Mark	Tilker
Michael	Vanderpol
Marcus	Wilson
Mackenzie	Young
Nicolas	Gamble
Noli	Gipa
Nelia	Kersey
Naquila	Langley
Norma	Phillips
Nike	Vinzant
Olivia	Cope
Octavia	Smith
Pamela	Anderson
Paula	Belle
Paul	Dickson Jr
Pamela	Edmonson
Patrick	Harris
Pamela	Hopkins
Patrick	Kennedy
Peyara	Lee
Pamela	Melancon
Pierre	Mosely
Patrick	Rhodes
Priscilla	Scott
Paula	Thomas
Patricia	Tokoi
Rantonia	Bishop
Reed	Bison
Rita	Black
Ronald	Causey
Richard	Chellette
Robert	Darwent
Rodetra	Dickerson
Ronny	Franke
Rodrick	Frierson
Raymon	Gilmore
Ronnie	Granados
Russell	Henry
Rustin	Holbert

Rayvene	Hunt
Richard	Khelama
Robert	Lane
Rupert	Lange
John	Haley
Rebecca	Malone
Raleigh	Moore
Ricky	Plunkett
Randi	Reliford
Russell	Salley
Robin	Smith
Rodney	Stills
Raynekia	Thomas
Ryan	Wagner
Robert	Wilcox
Roushanda	Wilson
Shatora	Baylor
Samantha	Brown
Shonteal	Butcher
She"Marian	Demery
Steven	Griffith
Shakayla	Harris
Susie	Irelan
Sue	Jones
Skye	Jousma
Stephanie	Littleton
Stephanie	Maeshack
Sandhya	Maramraj
David	Mitchell
Shannon	Moffett
Shaylon	Newton
Sarah	Palmer
Sylvia	Presswood
Sirquetta	Reliford
Sarah	Robertson
Shakira	Smith
Stephen	Smith
Sherry	Stevens
Sharon	Stokes
Selerie	Thomas
Stephen	Walsh
Steven	Williams
Ted	Adams
Thomas	Ball
Tim	Beaver
Tylar	Bogan
Tashe	Bright

Tiffany	Brown
Timothy	Chapman
Thailan	Clark
Tamiko	Davis
Timothy	Ditto
Tyrone	Emerson
Tadarius	Gipson
Tyler	Harman
Theresa	Henry
Tarsha	Houston
Taquanteeyus	Hynes-Bickham
Ty'Mere	Jackson
Tremayne	Jackson
Tyler	Johns
Tonette	Jones
Trina	Lacour
Tammy	Lorden
Timothy	Mcnaughton
Theresa	Morrison
Trey	Parks
Tristan	Parrie
Trinity	Peebles
Toronda	Pouncy
Tracee	Richmond
Timothy	Sizemore
Terry	Sparks
Thomas	Tingstrom
Tiara	Tolliver
Trevor	Upton
Thien	Vo
Timothy	Wallis
Terry	Wells
Tonya	Yarbrough
Uriel	Salazar
Vincent	Hartline
Valerie	Mcgill
Vera	Mcnaughton
Vincent	Peters
Vanessa	Rawlins
William	Banta
Warren	Beene
Whitney	Brimmer
Walter	Howell
Whittney	Meeler
Wanda	Parker
William	Porter
Wanda	Watson

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816
(225)295-8567 (225)295-8568 admin@drugboard.la.gov www.drugboard.la.gov

INSPECTION REPORT - Page 1 of 4

License / Application #:	4299	**Inspection Date:**	11/30/2022
Licensed Facility Name:	MORRIS & DICKSON CO., LLC.	**License Type:**	S, W, 3PL
Facility Address:	10301 Highway 1 South Shreveport, LA 71115	**Product:**	LD, CS, DV
		Designated Responsible Party:	Alan Bass

Facility Changes Since Last Inspection?			Outstanding Violations?			Previous Thefts or Losses of Product?		
Yes	No	N/A	Yes	No	N/A	Yes	No	N/A
	N			N			N	

		Yes	No	N/A	Comments
1.	Is DRP available for inspection or on authorized leave/absence? [LAC 46:XXXIV.305.D.1.e]	Y			
2.	Current LBDDD license displayed [LAC 46:XXXIV.301.G]	Y			
3.	Has off-site storage facility (ies) [LAC 46:XXXIV.301.K]		N		
4.	Facility is of suitable size and Construction [LAC 46:XXXIV.309.A.1.a]	Y			
5.	Facility is clean and orderly [LAC 46:XXXIV.309.A.1.d]	Y			
6.	Facility is free from infestation by insects, rodents, birds, or vermin of any kind [LAC 46:XXXIV.309.A.1.e]	Y			Eco-Lab
7.	Storage provides adquate: [LAC 46:XXXIV.309.A.1.b]				
	a. Lighting	Y			
	b. Ventilation	Y			
	c. Temperature	Y			
	d. Sanitation	Y			
	e. Humidity	Y			
	f. Space	Y			
	g. Equipment	Y			
	h. Security Conditions	Y			
8.	Storage area has a designated and clearly identified quarantine area for storage of drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened [LAC 46:XXXIV.309.A.1.c]	Y			Quarantine Room w/signs
9.	Storage facility has a working monitored alarm system or (medical gas only) is a board approved facility kept under lock and key [LAC 46:XXXIV.309.A.2.b&c]	Y			Centurytel monitoring
10.	Medical Gases only distributors that store medical gases on an open dock shall be equipped with a monitored alarm system [LAC 46:XXXIV.309.A.2.d]			N/A	No medical gases

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INSPECTION REPORT - Page 2 of 4

License / Application #:	4299	**Inspection Date:**	11/30/2022
Licensed Facility Name:	MORRIS & DICKSON CO., LLC.	**License Type:**	S, W, 3PL
Facility Address:	10301 Highway 1 South	**Product:**	LD, CS, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

		Yes	No	N/A	Comments
11.	Facility equipped with monitored security system suitable for protection againt theft or diversion and provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records [LAC 46:XXXIV.309.A.2.e]	Y			Computers password protected
12.	Drug or Device products are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or devices or in compliance with an official compendium [LAC 46:XXXIV.309.A.3]	Y			"Sonic U" digital monitoring & recording
13.	Facility utilizes appropriate electromechanical or electronic temperature recording equipment, devices, and logs approved by the LBDDD [LAC 46:XXXIV.309.A.3.b]	Y			
14.	Inventory records readily available for inspection for three years following disposition of the drugs or devices at issue [LAC 46:XXXIV.311.A&C]	Y			
15.	Financial records readily available for inspection for three years from the date each record was created [LAC 46:XXXIV.311.B]			N/A	
16.	Perpetual inventories and records maintained of all transactions regarding the receipt, distribution, or other disposition for all drugs, devices, and or medical gases are current [LAC 46:XXXIV.311.A]	Y			
17.	Temperature monitoring logs are maintained and current (excluding medical gasses only) [LAC 46:XXXIV.309.A.3.b]	Y			
18.	Copies of customer licenses verifying authority to procure or possess drug products or devices on file and current or if maintained off site, a copy of the customer list [LAC 46:XXXIV.311.E]	Y			
19.	Has verified all suppliers are licenced by LBDDD [LAC 46:XXXIV.311.G]	Y			
20.	Has established and maintains policies and procedure [LAC 46:XXXIV.313]	Y			
	a. Receipt of drug, devices and/or medical gases [LAC 46:XXXIV.313.A]	Y			
	b. Storage [LAC 46:XXXIV.313.A]	Y			
	c. Security [LAC 46:XXXIV.313.A]	Y			
	d. Inventory [LAC 46:XXXIV.313.A]	Y			
	e. Distribution [LAC 46:XXXIV.313.A]	Y			
	f. Correction of inventory errors and inaccuracy [LAC 46:XXXIV.313.A]	Y			
	g. Inspection of all incoming & outgoing shipments [LAC 46:XXXIV.313.A.5]	Y			

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INSPECTION REPORT - Page 3 of 4

License / Application #:	4299	**Inspection Date:**	11/30/2022
Licensed Facility Name:	MORRIS & DICKSON CO., LLC.	**License Type:**	S, W, 3PL
Facility Address:	10301 Highway 1 South	**Product:**	LD, CS, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

		Yes	No	N/A	Comments
	h. Product rotation to ensure distribution of oldest approved stock [LAC 46:XXXIV.313.A.1]	Y			
	i. Recalls and withdrawals [LAC 46:XXXIV.313.A.2]	Y			
	j. Out-dated drug or device segregation; Return or destruction; 3-year record retention [LAC 46:XXXIV.313.A.4]	Y			
	k. Validation of customer licenses [LAC 46:XXXIV.313.A.5]	Y			
	l. Notification within 3 business days of theft or diversion [LAC 46:XXXIV.313.A.6]	Y			
	m. Preparation and protection against any crisis that affects security or operation of facility in event of strike, fire, flood, or other situations of local, state, or national emergency [LAC 46:XXXIV.313.A.3]	Y			
	n. Notification within 24 hours of discovery of contraband, counterfeit or misbranded drugs [LAC 46:XXXIV.313.A.7]	Y			
	o. Verification of suppliers [46:XXXIV.311.G]	Y			
	p. Review of excessive or suspicious purchases [LAC 46:XXXIV.313.A.5]	Y			
	q. Monitoring & recording of storage temperatures [LAC 46:XXXIV.313.A.5]	Y			
21.	Maintains on-site current list of responsible persons, owners, officers, directors, manager, and designated responsible party [LAC 46:XXXIV.315.A]	Y			
	a. List of employees with access to product	Y			
	b. List of employees with access to building after hours	Y			
22.	Facilities handling controlled substances				
	a. Has current CDS registration.	Y			
	b. Has current DEA registration.	Y			
	c. Arcos reports submitted.	Y			
	d. Suspicious Excessive reports submitted.	Y			

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INSPECTION REPORT - Page 4 of 4

License / Application #:	4299	**Inspection Date:**	11/30/2022
Licensed Facility Name:	MORRIS & DICKSON CO., LLC.	**License Type:**	S, W, 3PL
Facility Address:	10301 Highway 1 South Shreveport, LA 71115	**Product:**	LD, CS, DV
		Designated Responsible Party:	Alan Bass

Notes:
None

The signature of licensee representative only validates that an inspection took place.

Licensee Representative — 11/30/2022 Date

Inspector's Signature — 11/30/2022 Date

M&D Specialty Distribution, L.L.C.

January 16, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: M & D Specialty Distribution, L.L.C. Pending Initial Wholesale Drug Distributor Application

Dear Licensing Authority,

This letter provides information supplementing the above pending applications submitted by M&D Specialty Distribution, L.L.C. ("MDSD"), a pharmaceutical wholesaler located in Shreveport, Louisiana.

MDSD is not a distributor of controlled substances. MDSD is contractually affiliated and has overlapping ownership with Morris & Dickson Co., LLC ("M&D Co."), which also is a pharmaceutical wholesaler located in Shreveport, Louisiana. M&D Co.'s business includes the distribution of controlled substances. M&D Co. has settled an administrative proceeding with the United States Drug Enforcement Administration concerning events between 2014 and 2018 (the "2018 Proceeding"), pursuant to a Settlement and Administrative Memorandum of Agreement (the "MOA"). M&D Co. has provided a copy of the MOA to the Board. The MOA does not pertain to MDSD.

Should your agency require any additional information, please direct any inquiries regarding this matter to:

Paul Weinstein, Esq.
Outside General Counsel
Emmet, Marvin & Martin, LLP
120 Broadway, 32nd Fl.
New York, NY 10271
pweinstein@emmetmarvin.com

Thank you for your assistance in this matter,

M&D Specialty Distribution, L.L.C.

Morris & Dickson

January 16, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: Morris & Dickson Co., L.L.C., Pending Initial Wholesale Drug Distributor Application

Dear Licensing Authority,

This letter provides information supplementing the above pending applications submitted by Morris & Dickson Co., L.L.C. ("M&D Co."), a pharmaceutical wholesaler located in Shreveport, Louisiana. M&D Co. has settled an administrative proceeding with the United States Drug Enforcement Administration concerning events between 2014 and 2018 (the "2018 Proceeding"), pursuant to a Settlement and Administrative Memorandum of Agreement (the "MOA"). A copy of the MOA is attached to this letter. The 2018 Proceeding has been the subject of prior reporting to the Board. It is requested that the MOA remain confidential with the Board.

The MOA permits the full continuation of M&D Co.'s business in all respects. Terms of the MOA include a payment to the DEA and M&D's maintenance of its existing compliance policies and procedures. M&D Co. distributes controlled substances from its Shreveport, Louisiana facility pursuant to that facility's DEA registration (the "M&D Co. DEA Registration"). Pursuant to the MOA, M&D Co. maintains the M&D Co. DEA Registration.[1]

Should your agency require any additional information, please direct any inquiries regarding this matter to:

Paul Weinstein, Esq.
Outside General Counsel
Emmet, Marvin & Martin, LLP
120 Broadway, 32nd Fl.
New York, NY 10271
pweinstein@emmetmarvin.com

Thank you for your assistance in this matter,

Morris & Dickson Co., L.L.C.

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[1] The company is surrendering a separate DEA registration for a facility in Jefferson, Louisiana, which, for in excess of the past 10 years, has been operated by M&D Co. dba Spark Drug (the "Spark Facility"), solely for the purpose of distributing non-controlled drugs to certain customers within Louisiana. Thus, the Jefferson, Louisiana DEA registration has not been used by M&D Co. for over 10 years. The surrender of the Jefferson, Louisiana DEA registration will have no effect on M&D Co.'s business. The Spark Facility is not the subject of the above-referenced pending license application(s).

January 12, 2024 Settlement and Administrative Memorandum of Agreement

SETTLEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Morris & Dickson Co., LLC ("M&D") (each a "Party" and collectively the "Parties").

This Agreement shall be applicable to M&D and any facility owned or operated by M&D that is registered, or that may become registered, with DEA to distribute or otherwise handle controlled substances.

I. RECITALS

1. In order to avoid the uncertainty and expense of continued litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further below, including without limitation M&D's appeal pending in the Court of Appeals for the Fifth Circuit. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of this matter.

2. M&D owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances, Registration Nos. RM0314790 and RM0335732 (together the "COR") under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. ("CSA") (each a "Distribution Center" and collectively the "Distribution Center").

3. The DEA is the Department of Justice component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

4. The regulations promulgated under the CSA require registrants to design and operate a system to detect and report "suspicious orders" for controlled substances, as defined in the regulations. *See* 21 C.F.R. § 1301.74(b).

5. On or about May 2, 2018, DEA served M&D with an Order to Show Cause ("OTSC") and Immediate Suspension of Registration ("ISO"), immediately suspending M&D's COR, pursuant to 21 U.S.C. § 824(d), and proposing to revoke its COR and deny any pending

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applications for renewal or modification, pursuant to 21 U.S.C. §§ 824(a)(4) & 823(b).

6. On or about May 5, 2018, M&D obtained a temporary restraining order prohibiting DEA from enforcing the ISO (the "TRO").

7. On or about May 18, 2018, Acting Administrator Robert W. Patterson rescinded the ISO, but left the Order to Show Cause in place.

8. On May 13-16, 2019, DEA held an administrative hearing on the Order to Show Cause before Administrative Law Judge ("ALJ") Charles W. Dorman (the "ALJ Hearing").

9. On or about August 29, 2019, ALJ Dorman issued a Recommended Rulings, Findings of Facts, Conclusions of Law, and Decision ("R&R"). In the R&R, he recommended that both of M&D's CORs be revoked.

10. On or about May 19, 2023, Administrator Anne Milgram issued a Decision and Order ("Final Order") revoking both of M&D's CORs, effective thirty days from the Final Order's publication in the Federal Register.

11. On May 23, 2023, the Administrator modified her decision to allow M&D ninety days to attempt to reach a settlement with the Agency.

12. On or about May 30, 2023, the Final Order was published in the Federal Register.

13. On or about June 2, 2023, M&D petitioned the Court of Appeals for the Fifth Circuit for a stay of the effective date of the Final Order.

14. On or about June 16, 2023, the Fifth Circuit granted M&D's request for a full stay of the effective date of the Final Order pending a decision on the merits.

II. TERM OF AGREEMENT

15. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the effective date of this Agreement unless DEA agrees in writing to an earlier termination.

III. ACCEPTANCE OF RESPONSIBILITY

16. M&D acknowledges and unconditionally accepts responsibility for every CSA violation found by the Administrator in the Agency's Final Order (the "Covered Conduct"). See Final Order attached as **Appendix A**.

IV. COMPLIANCE ADDENDUM

17. Simultaneous with the execution of this Agreement, M&D and DEA have entered into a Compliance Addendum, which is attached as **Appendix B**.

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V. REGISTRATION CONSEQUENCES

18. M&D agrees to immediately surrender for cause its DEA Certificate of Registration No. RM0335732.

19. Following the surrender for cause of DEA Certificate of Registration No. RM0335732, M&D shall respond in the affirmative to any and all questions on Federal or State application and registration application concerning whether M&D has been subject to liability.

20. As to DEA Certificate of Registration RM0314790, M&D and DEA stipulate that:

a. Revocation of DEA Certificate of Registration RM0314790 was the proper remedy for the Covered Conduct;

b. In the period between DEA's ISO and OTSC and the Final Order, M&D expended substantial resources to remediate its compliance program.

c. DEA Certificate of Registration RM0314790 was suspended during the period between the ISO and the TRO. This suspension, together with M&D's surrender of DEA Certificate of Registration No. RM0335732, is a sufficient registration consequence considering:

i. The extended passage of time between the issuance of the ISO and the Final Order;

ii. The substantial resources M&D spent to remediate its compliance program with respect to suspicious orders and due diligence;

iii. M&D's agreement to enter a five-year Compliance Addendum;

iv. M&D's good faith anti-diversion efforts in the pre-ISO period, including its destruction (rather than sale) of $2.5 million of short-dated opioids; and

v. M&D's agreement to the payment terms set forth in this Agreement.

VI. TERMS AND CONDITIONS

21. In consideration of the mutual promises, covenants, and obligations set forth herein, DEA and M&D agree as follows:

a. M&D shall pay a total of Thirty-three Million Dollars ($33,000,000.00), which includes:

i. Fourteen Million Dollars ($14,000,000.00) of costs M&D incurred to enhance its compliance system between the date of the ISO and the present, which DEA agrees is hereby credited to the amount in paragraph

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21(a) above.

ii. M&D shall pay an additional Nineteen Million Dollars ($19,000,000.00) to DEA/Department of Justice consistent with the terms set forth below:

a) DEA will initiate administrative forfeiture proceedings against the $19 million based on the probable cause established in the May 19, 2023, Final Order executed by DEA Administrator Anne Milgram. This amount will be paid in five equal annual installments, beginning in 2025. For clarity, and as agreed by the parties, these payments totaling $19,000,000.00 are paid by M&D as remediation for M&D's alleged violations of the law resulting in alleged damage or harm.

b) Upon completion of the forfeiture proceedings, all forfeited proceeds will be disposed of according to the applicable Federal law.

c) Morris & Dickson Co., LLC waives any right to administrative or judicial notice of the forfeiture proceedings regarding the five annual payments, totaling $19 million, and further agrees to abandon and forfeit any interest they may have in each payment when made in the entirety of the $19 million once all payments are complete.

d) Each annual payment shall be made by cashier's check at the DEA New Orleans Field Division on the first business day after January 1, beginning in 2025.

c. Any material breach by M&D of this Agreement or the Compliance Addendum may be a basis upon which DEA takes administrative action against M&D. However, nothing in this Agreement shall be deemed a waiver of M&D's due process rights. Further, DEA hereby agrees to provide M&D a thirty (30) day safe harbor period to allow M&D the opportunity to cure any alleged breach before it initiates any administrative action.

d. In consideration of the fulfillment of the obligations of M&D under this Agreement, DEA agrees to:

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i. Fully and finally release M&D, together with its parent and subsidiary entities, facilities, registrants, officers, directors, employees, successors, attorneys, assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct through December 31, 2021, which the DEA asserted, or could have asserted based upon information that was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the effective date of this Agreement, and the review of the reports and records of M&D submitted to DEA prior to the effective date of this Agreement; and

ii. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, provided that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the effective date of this Agreement, and the review of the reports and records of M&D submitted to DEA prior to the effective date of this Agreement. This Release applies only to administrative actions brought before or by DEA with respect to the Covered Conduct.

e. M&D fully and finally releases DEA from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which M&D has asserted, could have asserted, or may assert in the future against DEA related to the Covered Conduct and DEA's investigation and prosecution thereof, including without limitations M&D's appeal pending before the Court of Appeals for the Fifth Circuit and its action pending against DEA in U.S. District Court for the Western District of Louisiana.

22. Except as expressly set forth herein, there are no additional promises, understandings, or agreements between M&D and DEA concerning any other administrative proceeding relating to any other federal, state, or local charges that may now be pending or hereafter be brought against M&D. Nor may any additional agreement, understanding, or

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condition relating to the Covered Conduct be entered into by M&D and DEA unless in writing and signed by both. However, the Parties acknowledge and agree that nothing herein conflicts with or modifies a separate nonprosecution agreement anticipated between M&D and the Department of Justice.

VII. MISCELLANEOUS

23. Binding on Successors. This Agreement is binding on M&D, and its respective successors, heirs, transferees, and assigns.

24. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

25. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

26. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transaction contemplated by this Agreement. M&D represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. M&D further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

27. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). DEA agrees to notify M&D immediately when the final signatory has executed this Agreement.

28. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, VA 22152; and

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Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.

b. For M&D:

Chief Compliance Officer
Morris & Dickson Co., LLC
410 Kay Lane
Shreveport, LA 71115

29. Disclosure. M&D and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

30. Confidentiality and Designation of Information. M&D and DEA agree that all reports submitted to DEA contain information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under FOIA and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide M&D reasonable opportunity to respond to any such requests.

31. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimile of signatures shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

32. Authorizations. The individuals signing this Agreement represent and warrant that they are authorized to execute his Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

33. Choice of Law and Venue. This Agreement shall be construed in accordance with the laws of the United States, and either party may seek judicial enforcement of this Agreement upon a material breach by the other party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

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34. Reservation of Rights: Nothing in this Agreement in any way limits, or is intended to limit, M&D's defenses against liability, based on factual or legal defenses, in any other pending or future litigation, other than in an action by DEA to enforce this Agreement.

35. M&D Standard Operating Procedures: M&D agrees to update its current Standard Operating Procedures to reflect the agreements herein.

IN WITNESS WHEREOF, M&D and DEA hereto have duly executed this Agreement by their authorized representatives.

Date: January 12, 2024

By

THOMAS PREVOZNIK

Digitally signed by THOMAS PREVOZNIK
Date: 2024.01.12 14:46:42 -05'00'

Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

Jim Walden
John Curran
Walden Macht & Haran
Counsel for Morris & Dickson

Appendix A
May 19, 2023 Order and May 23, 2023 Amended Order
Provided in earlier Submission/Notification

Appendix B
Compliance Addendum
Omitted from Submission as Proprietary and Confidential Information

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: M&D Specialty Distribution, L.L.C.

Physical Address: 10301 Highway 1 South, Suite 200

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 5145

City: Shreveport State: LA Zip: 71135

Telephone: 800-710-6100 Website: www.morrisdickson.com/md-specialty-distribution

Name of Designated Representative (DR): Alan Wayne Bass

Licensing Company Email: licensing@mdspecialtydist.com DR Email: licensing@mdspecialtydist.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: University Veterinary Research Centers		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please see attached narrative.

Original Signature (electronic, copies or stamps not accepted)

11/22/2023
Date

WLDT No. 2, L.L.C.

This narrative is submitted by WLDT No. 2, L.L.C. in connection with its response to Section 8, Questions 5 and 6 on its Personal History Application (the "Application") submitted to the Nevada State Board of Pharmacy.

The owners of M&D Specialty Distribution, L.L.C. ("MDSD") are individuals, partnerships, and L.L.C.s (collectively (the "MDSD Owners"). MDSD, a pharmaceutical wholesaler, has never distributed controlled substances. Some of the MDSD Owners also indirectly are owners of Morris & Dickson Co., L.L.C. ("M&D Co."). M&D Co. is also a pharmaceutical wholesaler, and its business includes the distribution of controlled substances.

Three limited liability companies, WLDT No. 2, L.L.C., WGDT No. 2, L.L.C. MADT No. 2, L.L.C. (together, the "L.L.C.s"), each have an approximate 3.6% indirect interest in M&D through the holding company Morris & Dickson Holding Co., L.L.C. ("Holdco"), which owns M&D Co., and an approximately 11.11% interest in MDSD. Therefore, on the Personal History Application for the L.L.C.s and Holdco, events relating to both MDSD and M&D responsive to Questions 5 and 6 of Section 8 of the Application are set forth below.

Events Concerning M&D Specialty Distribution, L.L.C.

Kansas 2022-12-06 Summary Order, $1,320.00 Civil Fine

In October 2022, MDSD applied to the Kansas State Board of Pharmacy ("KSBOP") for registration as a wholesale distributor. MDSD's license application was granted on December 6, 2022 (a copy of the December 6, 2022 Order is submitted with this Narrative as MDSD Exh. 1). As part of MDSD's license application, it informed KSBOP that between October 2021 and April 2022, prior to MDSD being licensed in Kansas, it had inadvertently shipped a quantity of Rabavert, a rabies vaccine, to an entity in the state. This occurred because Morris & Dickson Co., L.L.C. ("M&D Co."), which was and is licensed in Kansas and has overlapping ownership with and is contractually affiliated with MDSD, had supplied Rabavert to the customer previously. When M&D Co. discontinued the product, the product continued to be available through MDSD, and the Kansas entity ordered the product from MDSD. MDSD then mistakenly shipped the product to Kansas due to an error in software, which should have prevented the shipment to Kansas by MDSD. When MDSD discovered the error, it immediately ceased shipments to the Kansas entity and measures were implemented to prevent a recurrence in that and in all situations. In granting MDSD a wholesaler license in Kansas, KSBOP assessed a civil fine of $1,320.00 for the inadvertent shipments.

****

Events Concerning Morris & Dickson Co., L.L.C.

The below information pertains to M&D Co., and not to MDSD.

DEA Proceeding and New Suspicious Order Monitoring and Reporting protocols

Background

On May 2, 2018, approximately five years ago, the DEA commenced an administrative proceeding concerning M&D Co.'s controlled substance registrations (the "2018 Proceeding") by issuing an Order to Show Cause/Immediate Suspension (the "OTSC/ISO") against M&D Co.'s two registrations to distribute

controlled substances (the "DEA Registrations"). Six days later, on May 8, 2018, a federal district court judge issued a temporary restraining order against the DEA, ordering that M&D Co. may resume distributing controlled substances. Shortly thereafter, on May 18, 2018, the DEA ordered that the ISO was rescinded. M&D Co. has been fully operational and its DEA Registrations in place since that time.

The 2018 Proceeding concerned M&D Co.'s suspicious-order monitoring ("SOM") procedures between 2014 and 2018. Following the OTSC/ISO, M&D Co.'s SOM procedures were comprehensively restructured, a state-of-the-art system was implemented, and M&D Co. has operated in complete compliance with federal and state regulations in the half-decade following the OTSC/ISO. It has continued to do so to the present date.

Between May 13-17, 2019, an administrative hearing was conducted before a DEA Administrative Law Judge ("ALJ"). Following the 2019 hearing, and for the past approximately four years, negotiations were ongoing between M&D Co. and the DEA to resolve the 2018 Proceeding and, until May 19, 2023, four years after the hearing, as described below, the DEA Administrator did not issue a final order following the ALJ's 2019 confidential recommendation. During this five year period following the OTSC/ISO, M&D Co. continued to report to the DEA regarding its restructured SOM procedures, which the DEA has described as "impressive." This restructuring is summarized below, followed by a description of the DEA's May 19, 2023 order, which subsequently was amended by a further order from the DEA Administrator, dated May 23, 2023 (the May 19, 2023 order together with the May 23, 2023 order will be referred to below as the "May 19/23 Order").

2018 Restructuring of M&D Co.'s SOM Procedures

The primary basis for the DEA's OTSC/ISO was its view that prior to 2018 M&D Co. had failed to report suspicious orders and to conduct due diligence on certain identified customers. M&D Co. took the DEA's allegations and conclusions very seriously and immediately, in 2018, undertook a restructuring of its SOM procedures. At that time M&D Co. hired the Analysis Group ("AGI"), an experienced data analytics firm with expertise in controlled substance order monitoring to develop a statistical methodology for identifying orders of unusual size, frequency, or pattern. An interim version of the AGI model was put in place on May 24, 2018, less than a month following the OTSC/ISO, and the permanent model was implemented for all retail pharmacy customers on October 1, 2018, alternate care customers in January of 2019 and hospitals in May of 2019. Since the implementation of the interim AGI order monitoring system in 2018-2019, M&D Co. has reported on a daily basis all of the orders flagged by the system to the DEA's complete satisfaction.

In addition, in May 2018, the same month as the OTSC/ISO, M&D Co. hired Guidepost Solutions and its then-Senior Managing Director, Louis Milione to assist M&D Co. in the enhancement of its policies, procedures, and processes related to controlled substance monitoring. The Guidepost personnel were all former DEA Diversion Investigators, former Senior Attorneys, former DEA Special Agents and former state and local law enforcement officials and have been involved in overseeing M&D Co.'s compliance processes since May 2018. Guidepost and members of the M&D Co. Compliance Team have conducted enhanced due diligence, including site visits, on the entirety of M&D Co.'s customer base, which totals over 1,000 customers, with most being the subject of more than one site visit. Since the site visit project began, M&D Co. has terminated the supply of controlled substances to approximately 44 customers and declined to onboard 52 accounts. In August 2021, Mr. Milione left his position at Guidepost to rejoin the DEA as the Principal Deputy Administrator. Presently, Guidepost Senior Managing Director Krista Tongring is M&D Co.'s Interim Chief Compliance Officer.

Further, M&D Co. created an official regulatory affairs group under the leadership of a senior company executive and increased the full-time staff from 1 to its current 11 employees, in addition to Guidepost personnel. In connection with the new regulatory affairs group, M&D Co.'s IT department years ago implemented numerous enhancements to the electronic customer due diligence files from

which the regulatory affairs team makes its order review and other due diligence decisions. Training has been conducted for the new personnel regularly since 2018. All regulatory affairs personnel have been trained on DEA policies and procedures, and several of the team have attended DEA training for wholesale distributor registrants. A written manual of M&D Co.'s Standard Operating Procedures ("SOP") relating to customer due diligence and order review went into effect in May 2019 and was updated in July 2020; SOPs for M&D Co.'s hospital customers went into effect at that time as well.

The DEA Administrator's May 19, 2023 Order and May 23, 2023 Amended Order

In the 2018 Proceeding, on May 19, 2023 the DEA issued a Final Order and then an amended order dated May 23, 2023 revoking the controlled substance registrations of M&D Co. (the "May 19/23 Order," which is submitted with this Narrative as M&D Exh. 1(A)(the May 19, 2023 Order) and M&D Exh. 1(B)(the May 23, 2023 Order) respectively). The May 19/23 Order by its terms did not go into effect until 90 days following the filing of the May 19/23 Order in the Federal Register, which occurred on May 30, 2023. A purpose of the 90-day period prior to the May19/23 Order's effectiveness was to permit the DEA and M&D Co. to negotiate a settlement of the 2018 Proceeding.

The May 19/23 Order was issued five years after the commencement of the 2018 Proceeding, four years after the administrative hearing on the same, and was based solely on events prior to 2018. Furthermore, in the May 19/23 Order, the DEA Administrator determined that since 2018, M&D Co.'s controlled substance policies and procedures were "impressive." Notwithstanding that M&D Co. has been in regulatory compliance since 2018, and will continue to be in regulatory compliance, the May 19/23 Order concluded that M&D Co.'s registrations should be revoked for pre-2018 events.

Fifth Circuit Appeal

On May 30, 2023, before the United States Court of Appeals for the Fifth Circuit (the "Fifth Circuit"), M&D Co. filed a Petition challenging the May 19/23 Order as unjustified and improper. On June 2, 2023, M&D Co. sought a stay of the effectiveness of the Order from the Fifth Circuit for the entire duration of M&D Co.'s appeal (the "Stay Motion").

The Fifth Circuit granted the Stay Motion by Order dated June 16, 2023, (the "June 16, 2023 Stay Order," which is submitted with this Narrative as M&D Exh. 1(C)). The June 16, 2023 Stay Order's effect is to maintain M&D Co.'s DEA Registrations in force during the entirety of M&D Co.'s challenge to the May 19/23 Order. The June 16, 2023 Stay Order was premised upon the Fifth Circuit's determination that M&D Co. was likely to succeed in challenging the May 19/23 Order.

On November 3, 2023, a joint motion was made by the Department of Justice ("DOJ")/DEA and M&D Co. to suspend the litigation of the 2018 DEA Proceeding in the Fifth Circuit (the "Joint Motion to Suspend Litigation") because "the parties are in advanced stages of settlement negotiations and believe that they may be able to resolve the underlying dispute between them." In response to the Joint Motion to Suspend Litigation, on November 8, 2023, the Fifth Circuit issued an Order holding the entire proceeding before the Court in abeyance for a 90 day period "to facilitate settlement discussions" (the "November 8, 2023 Abeyance Order," which is submitted with this Narrative as M&D Exh. 1(D)). If the matter is not settled at the end of the 90 day period, proceedings before the Fifth Circuit would continue. During the entire period and until the end of the litigation, the June 16, 2023 Stay Order also will remain in place.

WDLA Settlement

Additionally, on May 24, 2019, M&D Co. agreed to pay a civil fine of $22 million to the Department of Justice in a settlement reached through the United States Attorney's Office for the Western District of

Louisiana ("WDLA Settlement," which is submitted with this Narrative as M&D Exh. 2). The WDLA settlement, which was not an admission of liability, was finalized and paid in full on May 24, 2019.

Alabama Proceeding

On March 29, 2021, the Alabama State Board of Pharmacy ("AL BOP") issued an Order to Show Cause requiring that M&D Co. show cause why its Alabama state license is relevant to and consistent with public health and safety of Alabama (the Alabama Order to Show Cause is submitted with this Narrative as M&D Exh. 3). The AL BOP attached the WDLA Settlement from 2018 as its only allegation against M&D Co.. M&D Co. opened a dialogue with then-current counsel for the AL BOP and voluntarily provided a litigation history and summary of its compliance program to the AL BOP. M&D Co. explained through written discourse that the WDLA Settlement contained no admissions of wrongdoing by M&D Co. and was simply a "pay for peace" type settlement. M&D Co. requested that the matter be favorably resolved prior to a hearing in light of M&D Co.'s submissions and willingness to be open and forthcoming with the AL BOP. Following the aforementioned dialogue, the AL BOP continued the matter for two years. Recently, new counsel at AL BOP has scheduled a hearing for February 20 2024, wherein, if the matter is not resolved prior to the hearing, M&D Co. will continue to assert that there is not now, nor has there ever been any basis for revocation. Since receiving notice from the AL BOP of the proceeding, in March 2021, M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Alabama and continues to hold that license to date.

Kentucky BOP Letter of Concern

On February 7, 2022, the Kentucky Board of Pharmacy ("KBOP") sent a letter to M&D Co., stating that it had reviewed the WDLA Settlement and the policies and procedures of M&D Co. both before and after the Settlement, and concluded that the issuance of a complaint was not appropriate (the Kentucky BoP Letter of Concern is submitted with this Narrative as Exh. M&D 4). The letter further stated that the KBOP "expressed concern" regarding the WDLA Settlement, but had determined that no other action was appropriate. M&D Co. believes that the February 7, 2022 letter concludes the review of the WDLA Settlement and M&D Co.'s policies and procedures by the KBOP. M&D Co. has at all times remained a licensed pharmaceutical distributor in the state of Kentucky and continues to hold that license to date.

Multi-District Litigation

M&D Co. has been named as a "distributor defendant" in approximately 225 cases which have been, or will be consolidated in the United States District Court for the Northern District of Ohio under Multi District Litigation No. 2804, the National Prescription Opiate Litigation. Though the cases are many, the allegations in these cases are materially the same, alleging that the manufacturers of prescription opioids grossly misrepresented the risks of long term use of those drugs for persons with chronic pain, and distributors failed to properly monitor suspicious orders of those prescription drugs, all of which contributed to the current national opioid epidemic. M&D Co. has been placed in a small distributors defendants class for purposes of negotiation or litigation, and to date all litigation has been stayed for M&D Co., and for the small distributors defendant class as a whole until resolution of the bellwether trials with the larger defendants has been reached. The complaints do not allege any specific allegations against M&D Co., but rather sweep the entire industry into a set the set of general allegations described above. If and when litigation begins for M&D Co., M&D Co. will deny the allegations alleged in each complaint. M&D Co. believes that the vast majority of this litigation will ultimately be resolved through settlement.

For exhibits referenced in this narrative, please see the exhibits attached to the Business narrative.

M&D Specialty Distribution, L.L.C.

This narrative is submitted by M&D Specialty Distribution, L.L.C. ("MDSD") in connection with its response to Section 2, Question 3 on its Wholesaler Application submitted to the Nevada State Board of Pharmacy.

Kansas 2022-12-06 Summary Order, $1,320.00 Civil Fine

In October 2022, MDSD applied to the Kansas State Board of Pharmacy ("KSBOP") for registration as a wholesale distributor. MDSD's license application was granted on December 6, 2022 (a copy of the December 6, 2022 Order is submitted with this Narrative as MDSD Exh. 1). As part of MDSD's license application, it informed KSBOP that between October 2021 and April 2022, prior to MDSD being licensed in Kansas, it had inadvertently shipped a quantity of Rabavert, a rabies vaccine, to an entity in the state. This occurred because Morris & Dickson Co., L.L.C. ("M&D Co."), which was and is licensed in Kansas and has overlapping ownership with and is contractually affiliated with MDSD, had supplied Rabavert to the customer previously. When M&D Co. discontinued the product, the product continued to be available through MDSD, and the Kansas entity ordered the product from MDSD. MDSD then mistakenly shipped the product to Kansas due to an error in software, which should have prevented the shipment to Kansas by MDSD. When MDSD discovered the error, it immediately ceased shipments to the Kansas entity and measures were implemented to prevent a recurrence in that and in all situations. In granting MDSD a wholesaler license in Kansas, KSBOP assessed a civil fine of $1,320.00 for the inadvertent shipments.

* * * * * * * * * * * * * * * *

Events Concerning Morris & Dickson Co., L.L.C.

Three of the owners of MDSD are individuals, partnerships, and L.L.C.s (collectively (the "MDSD Owners"). MDSD, a pharmaceutical wholesaler, has never distributed controlled substances. Some of the MDSD Owners also indirectly are owners of Morris & Dickson Co., L.L.C. ("M&D Co."). M&D Co. is also a pharmaceutical wholesaler, and its business includes the distribution of controlled substances.

The below information pertains to M&D Co., and not to MDSD. It is provided as part of this MDSD Application, because M&D Co. and MDSD have overlapping beneficial ownership and are contractually affiliated. Specifically, the limited liability companies WLDT No. 2, L.L.C., WGDT No. 2, L.L.C. MADT No. 2, L.L.C., each have an approximate 3.6% indirect interest in M&D through a holding company, and an approximately 11.11% interest in MDSD.

DEA Proceeding and New Suspicious Order Monitoring and Reporting protocols

Background

On May 2, 2018, approximately five years ago, the DEA commenced an administrative proceeding concerning M&D Co.'s controlled substance registrations (the "2018 Proceeding") by issuing an Order to Show Cause/Immediate Suspension (the "OTSC/ISO") against M&D Co.'s two registrations to distribute controlled substances (the "DEA Registrations"). Six days later, on May 8, 2018, a federal district court judge issued a temporary restraining order against the DEA, ordering that M&D Co. may resume distributing controlled substances. Shortly thereafter, on May 18, 2018, the DEA ordered that the ISO was rescinded. M&D Co. has been fully operational and its DEA Registrations in place since that time.

The 2018 Proceeding concerned M&D Co.'s suspicious-order monitoring ("SOM") procedures between 2014 and 2018. Following the OTSC/ISO, M&D Co.'s SOM procedures were comprehensively restructured, a state-of-the-art system was implemented, and M&D Co. has operated in complete compliance with federal and state regulations in the half-decade following the OTSC/ISO. It has continued to do so to the present date.

Between May 13-17, 2019, an administrative hearing was conducted before a DEA Administrative Law Judge ("ALJ"). Following the 2019 hearing, and for the past approximately four years, negotiations were ongoing between M&D Co. and the DEA to resolve the 2018 Proceeding and, until May 19, 2023, four years after the hearing, as described below, the DEA Administrator did not issue a final order following the ALJ's 2019 confidential recommendation. During this five year period following the OTSC/ISO, M&D Co. continued to report to the DEA regarding its restructured SOM procedures, which the DEA has described as "impressive." This restructuring is summarized below, followed by a description of the DEA's May 19, 2023 order, which subsequently was amended by a further order from the DEA Administrator, dated May 23, 2023 (the May 19, 2023 order together with the May 23, 2023 order will be referred to below as the "May 19/23 Order").

2018 Restructuring of M&D Co.'s SOM Procedures

The primary basis for the DEA's OTSC/ISO was its view that prior to 2018 M&D Co. had failed to report suspicious orders and to conduct due diligence on certain identified customers. M&D Co. took the DEA's allegations and conclusions very seriously and immediately, in 2018, undertook a restructuring of its SOM procedures. At that time M&D Co. hired the Analysis Group ("AGI"), an experienced data analytics firm with expertise in controlled substance order monitoring to develop a statistical methodology for identifying orders of unusual size, frequency, or pattern. An interim version of the AGI model was put in place on May 24, 2018, less than a month following the OTSC/ISO, and the permanent model was implemented for all retail pharmacy customers on October 1, 2018, alternate care customers in January of 2019 and hospitals in May of 2019. Since the implementation of the interim AGI order monitoring system in 2018-2019, M&D Co. has reported on a daily basis all of the orders flagged by the system to the DEA's complete satisfaction.

In addition, in May 2018, the same month as the OTSC/ISO, M&D Co. hired Guidepost Solutions and its then-Senior Managing Director, Louis Milione to assist M&D Co. in the enhancement of its policies, procedures, and processes related to controlled substance monitoring. The Guidepost personnel were all former DEA Diversion Investigators, former Senior Attorneys, former DEA Special Agents and former state and local law enforcement officials and have been involved in overseeing M&D Co.'s compliance processes since May 2018. Guidepost and members of the M&D Co. Compliance Team have conducted enhanced due diligence, including site visits, on the entirety of M&D Co.'s customer base, which totals over 1,000 customers, with most being the subject of more than one site visit. Since the site visit project began, M&D Co. has terminated the supply of controlled substances to approximately 44 customers and declined to onboard 52 accounts. In August 2021, Mr. Milione left his position at Guidepost to rejoin the DEA as the Principal Deputy Administrator. Presently, Guidepost Senior Managing Director Krista Tongring is M&D Co.'s Interim Chief Compliance Officer.

Further, M&D Co. created an official regulatory affairs group under the leadership of a senior company executive and increased the full-time staff from 1 to its current 11 employees, in addition to Guidepost personnel. In connection with the new regulatory affairs group, M&D Co.'s IT department years ago implemented numerous enhancements to the electronic customer due diligence files from which the regulatory affairs team makes its order review and other due diligence decisions. Training has been conducted for the new personnel regularly since 2018. All regulatory affairs personnel have been trained on DEA policies and procedures, and several of the team have attended DEA training for wholesale distributor registrants. A written manual of M&D Co.'s Standard Operating Procedures ("SOP") relating

to customer due diligence and order review went into effect in May 2019 and was updated in July 2020; SOPs for M&D Co.'s hospital customers went into effect at that time as well.

The DEA Administrator's May 19, 2023 Order and May 23, 2023 Amended Order

In the 2018 Proceeding, on May 19, 2023 the DEA issued a Final Order and then an amended order dated May 23, 2023 revoking the controlled substance registrations of M&D Co. (the "May 19/23 Order," which is submitted with this Narrative as M&D Exh. 1(A)(the May 19, 2023 Order) and M&D Exh. 1(B)(the May 23, 2023 Order) respectively). The May 19/23 Order by its terms did not go into effect until 90 days following the filing of the May 19/23 Order in the Federal Register, which occurred on May 30, 2023. A purpose of the 90-day period prior to the May19/23 Order's effectiveness was to permit the DEA and M&D Co. to negotiate a settlement of the 2018 Proceeding.

The May 19/23 Order was issued five years after the commencement of the 2018 Proceeding, four years after the administrative hearing on the same, and was based solely on events prior to 2018. Furthermore, in the May 19/23 Order, the DEA Administrator determined that since 2018, M&D Co.'s controlled substance policies and procedures were "impressive." Notwithstanding that M&D Co. has been in regulatory compliance since 2018, and will continue to be in regulatory compliance, the May 19/23 Order concluded that M&D Co.'s registrations should be revoked for pre-2018 events.

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Attachment to Narrative - M&D Specialty Distribution, L.L.C.

Table of Contents

Attachment Pertaining to M&D Specialty Distribution, L.L.C.

MDSD Exh. 1 – Kansas State Board of Pharmacy $1,320.00 Civil Fine

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Attachments Pertaining to Morris & Dickson Co., L.L.C.

DEA 2018 Proceeding

M&D Exh. 1(A) - May 19, 2023 Order

M&D Exh. 1(B) - May 23, 2023 Order

M&D Exh. 1(C) - June 16, 2023 Indefinite Stay Order

M&D Exh. 1(D) – November 3, 2023 Abeyance Order

M&D Exh. 2 - WDLA Settlement

M&D Exh. 3 - AL BOP Order to Show Cause

M&D Exh. 4 - Kentucky BOP Letter of Concern

MDSD Exh. 1 - Kansas State Board of Pharmacy $1,320.00 Civil Fine

800 SW Jackson St., Suite 1414
Topeka, KS 66612

Kansas
Board of Pharmacy

Phone: (785) 296-4056
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pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

December 6, 2022

M & D Specialty Distribution, LLC
10301 Highway 1 South
Shreveport LA 71115

RE: Case No. 22-275

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling $1,320. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-275
M & D Specialty Distribution, LLC	)	
	)	
Permit 5-119201	)	

SUMMARY ORDER

NOW, on this 6th day of December, 2022, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of M & D Specialty Distribution, LLC. ("Applicant"), for application for registration as a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On October 21, 2022, the Board received Applicant's application for registration as a wholesale distributor in the State of Kansas ("Applicant's Application").

2. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months." The form directs that if the applicant answered "yes," the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas."

3. In conjunction with Applicant's Application, Applicant provided requested copies of

shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 16 unique days during the previous the time period of October 2021 to April 2022.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Applicant's act of shipping into Kansas prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's Application pursuant to K.S.A. 65-1627(f).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of $1,320. Applicant has 30 days from the date of this order to pay the fine and the registration shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414,

Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

12/6/2022
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 6th day of December, 2022, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

M & D Specialty Distribution, LLC
10301 Highway 1 South
Shreveport LA 71115

Kansas Board of Pharmacy Staff

M&D Exh. 1(A) - May 19, 2023 Order

BILLING CODE: 4410-09-P

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

MAY 19 2023

Docket No. 18-31
MORRIS & DICKSON CO., LLC
DECISION AND ORDER

On May 2, 2018, the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause (OSC) and Immediate Suspension of Registration (ISO) to Morris & Dickson Co., LLC (Respondent), of Louisiana. Administrative Law Judge (ALJ) Exhibit (ALJX) 1, at 1. The OSC informed Respondent of the immediate suspension of its Certificates of Registration Nos. RM0314790 and RM0335732 (registrations)[1] and proposed their revocation pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) because it alleged that Respondent's continued registrations were inconsistent with the public interest. *Id.*

Respondent requested a hearing before a DEA ALJ, which was conducted from May 13 to May 16, 2019. On August 29, 2019, the ALJ issued a Recommended Decision (RD), which was transmitted to the Agency along with the administrative record on November 26, 2019.[2] The Agency has incorporated portions of the ALJ's RD herein.

The Government presented a *prima facie* case. Respondent ultimately admitted to and accepted some responsibility for its failures in effectively applying its customer due diligence in assessing orders of controlled substances, its failures to implement a suspicious order monitoring

[1] Respondent sought and obtained a temporary restraining order against enforcement of the ISO. *See* ALJX 89, at 7. On May 18, 2018, the DEA Acting Administrator rescinded the ISO issued on May 2, 2018. Tr. 12; *see Stip.* 26.
[2] On October 8, 2019, Respondent filed Exceptions to the Recommended Decision (Resp Exceptions) and on November 7, 2019, the Government filed a response to Respondent's Exceptions. On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. On January 14, 2022, the Government filed an opposition to this motion and on January 21, 2022, Respondent filed a Reply Memorandum in Support of its Motion to Reopen the Administrative Record. The Agency addresses the Exceptions throughout and the Motion to Reopen at the end of this Decision.

system "consistent with best practices for compliance," and its failures to adequately resolve red flags on orders that it shipped. *See infra* section V. Respondent also admitted that its three suspicious order reports to DEA during the relevant time period were insufficient. *Id.* Nonetheless, Respondent presented testimony and evidence aimed at rebutting the Government's case with regard to the scope of its regulatory noncompliance during the relevant time period.

After thoroughly reviewing the entire record, the Agency finds substantial record evidence that Respondent's continued registration is inconsistent with the public interest in light of the long-term, egregious failures of Respondent in its responsibility as a distributor to maintain effective controls against diversion of controlled substances. Furthermore, the Agency finds that Respondent has failed to demonstrate that the Agency should continue to entrust it with its controlled substance registrations.

I. SUMMARY OF THE ALLEGATIONS

1. The OSC primarily alleged that Respondent failed to maintain effective controls against diversion when it failed to report to DEA thousands of unusually large orders for hydrocodone and oxycodone, which constituted potential suspicious orders, and when it shipped orders to customers without resolving red flags of diversion or reporting the orders to DEA in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1) as well as 21 C.F.R. §§ 1301.71(a) and 1301.74(b). OSC, at 2. Further, the OSC alleged that Respondent failed to adequately design and operate a system to alert Respondent to suspicious orders of controlled substances and failed to report the suspicious orders to DEA in violation of 21 C.F.R. § 1301.74(b). *Id.*

2. The allegations included that, from January 2014 until April 2018, Respondent shipped approximately 7,000 unusually large orders of oxycodone and almost 5,000 unusually

large orders of hydrocodone. OSC, at 5; Govt Prehearing, at 8. During this time, Respondent filed a total of only three suspicious order reports with DEA.

3. Furthermore, the OSC alleged that, from approximately January 2014 to April 2018,[3] Respondent failed to carry out its due diligence and suspicious order monitoring policies and failed to conduct or failed to document the resolution of meaningful due diligence into orders placed by the following pharmacies: Wallace Drug Company, Inc.; Bordelon's Super-Save Pharmacy; Folse Pharmacy; Pharmacy Specialties Group, Inc.; Dave's Pharmacy; the Wellness Pharmacy, Inc.; Wilkinson Family Pharmacy; and Hephzibah Pharmacy, L.L.C. (hereinafter, the exemplar pharmacies).

II. THE WITNESSES

A. The Government's Witnesses

The Government presented its case through the testimony of six witnesses and the introduction of 70 exhibits. The Government's first witness was the Acting Section Chief of the Pharmaceutical Investigation Section of the DEA (the Section Chief), who testified generally regarding the regulatory requirements for distributors. Tr. 47-87. The Government also presented testimony from two Diversion Investigators (DI 1 and DI 2) regarding the history of the investigation and the identification of Government exhibits.[4] *See* RD, at 11-12 (citing Tr. 94-101; 144-177). Next, the Government presented testimony from the Chief of the Statistical Services Section of DEA, G.R., who was qualified without objection as an expert in "developing

[3] The allegations for three of the exemplar pharmacies only spanned a subset of this timeframe: Wellness Pharmacy, January 2014-December 2017; Wilkinson Family Pharmacy, January 2014-April 2017; Hephzibah Pharmacy, April 2017-May 2017. Govt Prehearing, at 3.

[4] The Government presented testimony from a third Diversion Investigator (DI 3) to rebut the testimony of Respondent's witness, however, the Agency agrees with the RD that the testimony of DI 3 was not essential to the case and is therefore not including it herein. RD, at 20.

and implementing statistical models and methods of analyzing large and complex data sets." RD, at 13 (citing Tr. 192). G.R. testified to the methodology he employed in analyzing the statistical data that was used by DEA in its determination that Respondent had failed to report suspicious orders.[5] RD, at 12-15 (citing Tr. 187-245). The Government also presented testimony from the Group Supervisor of the New Orleans Field Division (the GS), who was accepted as an expert in "the identification of common red flags suggestive of an illicit pharmaceutical operation and as well [as] with respect to the requirements imposed on DEA registrants to identify and investigate such red flags when they become aware of them." RD, at 16 (citing Tr. 282).[6]

B. Respondent's Witnesses

Respondent presented its case through the testimony of three witnesses and the introduction of ten exhibits. Respondent's first witness was Kenneth A. Weinstein, Tr. 501-689, who was the Vice President of the consulting firm Analysis Group, Inc. (AGI), and was accepted without objection as an expert in statistical analysis related to controlled substance distribution and in pharmacy ordering and inventory management. RD, at 22 (citing Tr. 513-14; 520-21). Weinstein authenticated Respondent Exhibit (RX) 14, pages 15-19, and RX 28 and 29. Tr. 506, 562-68. Weinstein testified generally regarding the use of the Tukey analytical model in developing Suspicious Order Monitoring systems and testified specifically regarding what he found to be deficiencies in G.R.'s statistical analysis in this case. Weinstein also testified regarding AGI's compliance work for Respondent after DEA had issued the OSC.

[5] G.R. testified that he had corrected DEA's admitted error in the calculations in the OSC, which applied a Three Interquartile Range (IQR) to the median of the data set, or the 50th percentile, instead of the 75th percentile, and as a result, produced a larger group of outliers. Tr. 204, 208-09. G.R. further acknowledged that the error was identified by Respondent's expert. Tr. 218.

[6] The Agency adopts the ALJ's credibility findings regarding the Section Chief, the DIs, G.R., and the GS. RD, at 11-12, 15, 19.

Respondent's second witness was Scott Irelan, Tr. 693-840, who had worked for Respondent for 31 years before becoming the Director of Corporate Compliance and Security in May 2018 after the OSC was issued. Irelan testified regarding his current role at Respondent, the remedial measures that Respondent had put in place since the issuance of the OSC, Respondent's preexisting compliance measures during the relevant time period, and Respondent's acceptance of responsibility.

Respondent's final witness was Louis Milione,[7] Tr. 841-1057, who was, at the time, the Senior Managing Director of Guidepost Solutions. Respondent hired Guidepost Solutions to enhance Respondent's compliance system. Tr. 878-79. Milione was previously the Assistant Administrator of the Diversion Control Division at DEA and was offered and accepted without objection as an expert "in diversion." Tr. 851. He testified regarding his factual interactions with Respondent during his tenure at DEA[8] and regarding the work Guidepost performed for Respondent to improve its compliance with DEA requirements.[9]

III. FINDINGS OF FACT

[7] Milione is currently the Principal Deputy Administrator of DEA. Despite his return to the Agency, it is noted that Milione has not had any contacts with the Administrator nor anyone participating in the decisionmaking in this matter about and due to his prior involvement with this case.

[8] Respondent presented evidence, including testimony from Milione, about a meeting with Respondent at Respondent's invitation that occurred in August 2016 when Milione was in the role of Assistant Administrator of the Diversion Control Division at DEA. Tr. 856-861; RX 21; RX 11 (PowerPoint slide deck). Milione testified that, at that meeting, he believed that Paul Dickson, Sr., was committed to his regulatory obligations and sincere. Tr. 873. The powerpoint slides from that meeting, which Respondent submitted into evidence, generally support Respondent's statements regarding the workings of its previous SOM at a high level and its termination of customers pursuant to its due diligence efforts. RX 11; *see infra* n.61 regarding termination of Respondent's customers, and *infra* n.89 regarding evidence of the sincerity of Paul Dickson, Sr.

[9] The testimonies of Weinstein, Milione, and Irelan are afforded full credibility in this Decision on all points that are within their expertise and relevant to the final decision as further found herein. This Decision has found all major points of conflict between the Government's and Respondent's witnesses to be largely irrelevant to the Agency's adjudication of the allegations. The Agency analyzes the evidentiary weight of portions of the testimony of these witnesses in balance with other evidence on the record where relevant. It is noted that, although Irelan's testimony regarding acceptance of responsibility is analyzed in the Sanction Section *infra*, it is afforded full credibility.

The Parties agree to 47 stipulations (Stips.), which are accepted as facts in these proceedings. The Agency incorporates all of these into the record—the most relevant of which are summarized here. *See* RD, at 33-38. Between January 2014 and May 2018, Respondent submitted a total of three suspicious order reports to DEA. Stip. 7. In this same approximate timeframe, Respondent supplied controlled substances, including oxycodone and hydrocodone, to Wallace, Bordelon's, Folse, Pharmacy Specialties, and Dave's pharmacies. Respondent also supplied Hephzibah with controlled substances, including oxycodone and hydrocodone, between April and May 2017, Wellness Pharmacy between January 2014 and December 2017, and Wilkinson[10] between January and April 2017. *See* Stips. 11-20. The timeframe of the allegations in the OSC are hereinafter referred to as "the relevant timeframe."

A. DEA's Investigation

In 2017, while investigating pharmacies in Louisiana selling high volumes of oxycodone and hydrocodone, the DEA New Orleans Division discovered that some of those pharmacies were supplied by Respondent. Tr. 92. During a subsequent audit, Respondent told DEA that it used Pro Compliance Reports and its employees to identify suspicious orders. Tr. 93.

DEA served Respondent with three separate subpoenas and several requests for clarification between February 1, 2018, and April 2018.[11] RD, at 44-50. The subpoenas related to Respondent's identification of suspicious orders, due diligence, internal investigations, and internal policies and practices, and also identified specific pharmacies. Government Exhibits (GX) 7, 8, 10, 12, 15. Respondent responded via letters and produced some documentation. For example, GX 9 contains an undated letter from Jacob Dickson, stating that Respondent submitted

[10] Wilkinson Family Pharmacy voluntarily surrendered its DEA Certificate of Registration for Cause. Stip. 20.
[11] The Agency adopts the findings of fact in the RD related to these subpoenas and Respondent's response and summarizes herein. RD, at 44-50.

only two suspicious order reports to DEA because it "utilizes a pro-active approach to avoid diversion of controlled drugs, including: screening new pharmacy customers; aggressively monitoring orders for controlled drugs; and eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments, fill prescriptions for the 'Holy Trinity' and/or other unacceptable practices." GX 9, at 1; Tr. 319. The undated letter also states that "DEA and applicable regulations do not require that a wholesale distributor maintain records of each and every internal investigation conducted on possible suspicious orders." GX 9, at 1-2 (emphasis in original); Tr. 319-20. The letter further explained that once Respondent has cleared a possible suspicious order, "no record is maintained." GX 9, at 2. The undated letter explained that Respondent used a "four-fold approach to monitor all prescription drug orders and detect unusual ordering patterns, amounts, and cash payments to identify potentially suspicious orders." GX 9, at 2; Tr. 321. The four-fold approach included: use of Pro Compliance Reports; preparing a Market Basket Report of each customer on a monthly basis; since April 2017, use of software that identifies orders that are more than 10 times the "average dosage units ordered on a given drug on a certain day with the last 90 days of ordering patterns of the same drug"; the experience of the employees who fill the orders for controlled substances; and the input of delivery drivers and salesmen. GX 9, at 3-4.

Government Exhibit 11 is Respondent's (signed by Paul Dickson) supplemental undated response to DEA following up on subpoenas issued to Respondent. Tr. 144-45, 324; GX 11, at 2. This response states that "[b]ecause formal records are not kept in the regular course of business on the investigation of orders which do not result in the finding of a 'suspicious order' per 21 C.F.R. § 1301.74, the email communications produced herewith represent the most responsive records maintained." GX 11, at 2; Tr. 324.

At the same time, Respondent produced an external hard drive containing documents in response to the February subpoenas. Tr. 146. Again, DEA emailed Respondent to ensure a complete response, which Respondent generally affirmed and also then provided a phone log[12] with the earliest entry dated January 5, 2016. GX 12-14. In response to the subpoena for policies and trainings, Respondent informed DEA that its training of employees on suspicious order monitoring "does not necessitate or result in the production of documents." GX 16, at 1. Respondent's reply included two policy and procedure documents, which Respondent described as containing "some limited direction as to suspicious order monitoring." *Id.*; Tr. 174-76; GX 17, 18.

B. General Regulatory Obligations

21 C.F.R. § 1301.74(b) requires distributors to

> . . . design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id.

Respondent received a copy of a letter sent on September 27, 2006, by DEA to distributors of controlled substances. Tr. 62-63; GX 3, at 1. The letter emphasized that "[d]istributors are, of course, one of the key components of the distribution chain. If the closed

[12] Regarding the exemplar pharmacies, the phone log contains two entries concerning the Pharmacy Specialties Group, with a DEA registration number ending in "589." GX 14, at 4, 31; GX 23, at 1. Those entries are dated March 7, 2016, and December 13, 2017. GX 14, at 4, 31. There is one entry concerning Dave's Pharmacy, with a DEA registration number ending in "386." GX 14, at 23; GX 24, at 1. That entry is dated February 16, 2017. GX 14, at 23. There are three entries concerning Hephzibah Pharmacy, with a DEA registration number ending in "695." GX 14, at 23, 26; GX 25, at 1. Those entries are dated March 17 and 21, 2017, and June 20, 2017. GX 14, at 23, 26. There are five entries concerning Wilkinson Family Pharmacy, with a DEA registration number ending in "198." GX 14, at 24; GX 27, at 1. Those entries are dated April 19, 20, 21, and 24, 2017. GX 14, at 24. There are three entries concerning Wallace Drugs, with a DEA registration number ending in "363." GX 14, at 31; GX 20, at 1. Those entries are all dated January 9, 2018. GX 14, at 31; RD, at n.12. *See supra* section III.D.

system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes." GX 3, at 1. The letter therefore, reminded distributors of their "responsibilities . . . in view of the prescription drug abuse problem our nation currently faces." *Id.* Further, the letter reminded distributors of their duty under the regulation to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and their duty to report suspicious orders to DEA upon discovering the suspicious order. *Id.* at 2. In addition, the letter reminded distributors of their duty to exercise due diligence to avoid filling suspicious orders. *Id.* Finally, the letter provided distributors with 14 examples derived from DEA investigations of a customer's behavior that might be indicative of diversion. *Id.* at 3. The letter states that these examples are not all-inclusive and that "[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. § 823(e)." *Id.* DEA sent the same letter a second time on February 7, 2007. Tr. 64-65; GX 69.

Government Exhibit 4 is a December 20, 2007 letter that the DEA sent to every distributor of controlled substances. Tr. 63-64; GX 4, at 1. The stated purpose of this letter was to again remind distributors of the requirement to inform DEA of suspicious orders. GX 4, at 1. The letter reminded distributors that in addition to "maintain[ing] effective controls against diversion," they are also required to "report suspicious orders of controlled substances." *Id.* The letter reminded registrants that the regulation requires that these orders be reported "<u>when discovered</u> by the registrant." *Id.* (emphasis in original). The letter also reminded distributors "that their responsibility does not end merely with the filing of a suspicious order report.

Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels" in accordance with their requirements to maintain effective controls against diversion in 21 U.S.C. § 823(e). *Id.* The letter also informed registrants that DEA interpreted the list of types of suspicious orders to be "disjunctive and [] not all inclusive." 21 C.F.R. § 1301.74(b).

DEA maintains an Automation of Reports and Consolidated Orders System (ARCOS). Tr. 69-70. Distributors are required to report to ARCOS all shipments of controlled substances in schedules I and II and all narcotic controlled substances in schedule III. Stip. 9; Tr. 70. In April 2008, DEA met with Respondent's President Paul Dickson, Sr., and discussed Respondent's legal obligations and requirements as a distributor, including suspicious order requirements, the need to know its customers, and the need to conduct due diligence. Tr. 67-68. At the time, DEA reviewed its ARCOS data with Respondent to show customers who had anomalies and to demonstrate "things that [Respondent] should be looking at and questioning [its] customers [about]." Tr. 68-69. In 2013 and 2015, DEA conducted distributor conferences and Jacob Dickson, Respondent's compliance officer,[13] attended both conferences. Tr. 66-67. Both sides also presented evidence about a meeting with Jacob Dickson, Paul Dickson Sr., C.G. (a former compliance officer at Respondent) and officials from DEA, including Milione, in which Respondent presented its Suspicious Order Monitoring (SOM) system to DEA. *See* RX 11 (powerpoint); *see supra* n.8.

Respondent filed three suspicious order reports during the relevant time period. Stip. 7. The first, dated April 7, 2014, states that "[a]t this time, and pending further review by you or

[13] The GS testified that "one time [Jacob Dickson] was marked as president and then in the other time it was compliance officer." Tr. 67. In a letter to DEA in response to subpoenas, Jacob Dickson's title was listed as Vice President, SOM Manager. GX 9, at 4.

M&D, M&D has stopped selling schedule II through schedule V drugs to the captioned pharmacy." GX 6, at 1. The next report is dated April 26, 2017, and states that the pharmacy in question "purchased a quantity of 60 cartons of prefilled 10 mg morphine sulphate syringes . . . This was a substantial increase over a total sales of one carton in the prior four months." GX 6, at 35. The letter states that the order was investigated but does not discuss the resolution of this investigation, nor whether the order was filled. *Id.* The final report was filed on the same day, April 26, 2017, and gives no facts related to what order was deemed suspicious nor any information about an investigation or whether the order was shipped. GX 6, at 36.

Distributors are required to design and operate a suspicious order monitoring system that identifies suspicious orders. 21 C.F.R. § 1301.74(b). Suspicious orders include, but are not limited to, three stated criteria: orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.*

Additionally, a distributor's general duty to prevent diversion includes the duty to perform due diligence on its customers. *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487, 36,500 (2007); *see also Masters Pharmaceuticals, Inc.*, 80 Fed. Reg. 55,418, 55,476 (2015), *pet. for review denied, Masters Pharmaceuticals, Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). The GS testified that if the required due diligence at the customer level identifies red flags indicative of diversion, Tr. 328, those red flags render an individual order suspicious and trigger the investigation or reporting requirement, even if the regulatory criteria in 21 C.F.R. § 1301.74(b) are not present, e.g., the order size is not unusual. Tr. 477-478; *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (stating that "an order is not only suspicious by virtue of its internal properties—i.e., being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]").

The Agency's decision in *Masters* sets forth that a distributor must either investigate suspicious circumstances on an order and resolve all indicia of diversion or decline to fill the order and report it to DEA. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478.

C. Red Flags—Customer Due Diligence

The record evidence establishes that customer red flags indicative of potential diversion include a pharmacy customer that: dispenses a high volume of narcotics; dispenses the trinity drug cocktail;[14] dispenses disproportionally more controlled substances than non-controlled substances;[15] fills prescriptions for customers who live far away from the pharmacy; fills prescriptions for a high volume of patients who pay for prescriptions in cash;[16] fills prescriptions

[14] The trinity drug cocktail consists of an opioid, such as hydrocodone, a benzodiazepine, such as alprazolam, and a muscle relaxer, such as Soma, and the combination of substances is still a red flag even if each element is prescribed by different prescribers. Tr. 55, 300, 344.

[15] The record contains varying evidence as to the threshold percentage of a pharmacy customer's controlled substance fills relative to its non-controlled substance fills that would trigger a red flag for the distributor. *See* Tr. 351, 461 (The GS testifying that if the percentage of controlled substance prescriptions filled exceeds 15 percent of total prescriptions, it is a red flag); Tr. 1030 (Milione testifying that if a pharmacy is filling controlled substance prescriptions at a percentage exceeding the national average, then the distributor can resolve the red flag without reporting a suspicious order); Tr. 867 (Irelan testifying that the previous SOM system involved monitoring "for customers that were getting a little closer to 20 percent of that ratio"); RD, at n.5 (noting that the *Masters* decision found the threshold to be around 20 percent for controlled versus 80 to 90 percent for non-controlled, *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,480, but finding that the GS presented the most credible evidence at 15 percent).

The Agency finds the exact percentage threshold to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. Furthermore, all of the pharmacy customers in the allegations were dispensing controlled substances at 20 percent or more of their total dispensing—with one customer at one point dispensing as high as 69 percent controlled substances, *see* GX 26, at 11 (Wellness). The only exception was Bordelon's dispensing at 17 percent controlled substances, but which Pro Compliance reported as being "slightly higher than national average." GX 21, at 6. Furthermore, seven of the eight exemplar pharmacies demonstrated multiple red flags in addition to this one. It is indisputable that Respondent was aware of this red flag for each of these customers at a customer level due to the Pro Compliance Reports in its possession.

[16] The record contains varying evidence as to the threshold percentage of cash payments for controlled substance prescription fills at a pharmacy customer that would trigger a red flag for the distributor. *See* Tr. 328 (The GS testifying that any pharmacy customer exceeding 9 percent cash payments from customers should raise red flags); *see also* 1036-37 (Milione testifying that a high percentage of cash in controlled versus non controlled prescriptions is a red flag, but can be resolved with due diligence, the records of which must be maintained); Tr. 681 (Weinstein testifying that if a pharmacy has "a substantially higher percentage of cash payments for controlled substances than it did for a non-controlled substances, that would be a [potential] red flag of diversion," but that he does not have "a particular definition of substantial or significant," because it was more of a "relative comparison"); *but see* Tr. 649 (Weinstein answered that it was "fair" to say that when a distributor becomes aware of factors, such as cash payments, "they're significant red flags of diversion.").

for practitioners whose DEA registrations cannot be verified;[17] fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers; and/or orders excessive quantities of a limited variety of controlled substances. Tr. 297, 299-301, 335, 411, 427, 489-90, 648-49, 681, 1037; *see also* Pro Compliance Reports GX 20-56. Weinstein noted that red flags are visible in a pharmacy's dispensing data and not its ordering data.[18] Tr. 679. Irelan admitted that, during the relevant time period, due diligence was not being applied at the ordering level.[19] Tr. 722-23.

Again, the Agency finds the exact percentage threshold for cash payments to be largely irrelevant to determine in this case, because in every instance of the Government's allegations, this particular red flag was flagged by the Pro Compliance Reports that were created for Respondent. As detailed herein, the percentages of cash paid by Respondent's customers at issue were also particularly high, *see, e.g.*, 41 percent, GX 22, at 12 (Folse). It is indisputable that Respondent was aware of this red flag for each of these customers at a customer-level based on the Pro Compliance Reports in its possession.

[17] The Pro Compliance Reports additionally contain reports of prescribers whose DEA controlled substance registrations "could not be verified through DEA-Verify.com" and whose controlled substance prescriptions were filled by Respondent's customers. *See, e.g.*, GX 22, at 17; Tr. 336 (June 2017 Report showing that Folse filled controlled substances prescribed by 23 practitioners whose registrations could not be verified). Both Irelan and Milione testified that the portion of the Pro Compliance Reports concerning the verification of prescriber DEA numbers is unreliable. Tr. 765-66, 797, 901. Milione also testified that a distributor needs to hold and report a suspicious order if it is aware that a customer is filling prescriptions for a practitioner with no DEA registration. Tr. 1025. Although the Agency agrees with the RD, at n.14, that during the relevant timeframe, there is no evidence in the record that Respondent resolved the red flags presented by these reports demonstrating unverified registrations, even if they were unreliable, the Agency also finds that there is more than enough evidence on the record that Respondent did not resolve the other clearly established red flags of diversion and therefore finds it unnecessary to address these additional red flags in this Decision.

[18] The fact that the red flags applied to the customer generally and not to each individual order, *see* ALJX 89, at 99, is irrelevant to this adjudication, because under the relevant legal requirements, Respondent cannot ignore red flags that demonstrate that its customers are potentially diverting controlled substances and continue to fill those individual orders without resolving each of those red flags. *See* Tr. 477-478. At a minimum, Respondent must either have stopped the shipments and reported orders to DEA or resolved and documented each of the red flags. *See Masters Pharm., Inc.*, 861 F.3d at 222-23.

[19] It is noted that Respondent attempted to introduce and the ALJ rejected, Exhibit 32C, based on lack of identification. Tr. 447. Respondent's stated purpose was to impeach the Government's witness in demonstrating that Respondent's due diligence files did include photographs as described in its policy, Tr. 447, contrary to the GS's testimony that he did not "recall any" photographs, Tr. 322; RX 32C. The GS testified credibly that he did not recall seeing the file with the photograph "at all." Tr. 447. The Agency has reviewed the document and notes that it did include a photograph; however, the Agency is not finding that Respondent's compliance with its policy on this issue is relevant to this decision and, therefore, the exhibit marked for identification as RX 32C plays no role in the adjudication of this matter. Further, if this exhibit had been included in the record, standing alone, it bodes poorly for Respondent concerning its failure to report suspicious orders for terminated customers. *See infra* n.61.

The GS testified that when Respondent received the Pro Compliance Reports in GX 20-56 that demonstrated red flags of diversion, it was obligated to resolve the red flags and document their resolution. Tr. 474-76. Based on the record testimony of the experts, and the *Masters* decision, the Agency finds that when a distributor is aware of red flags indicating diversion of controlled substances from a customer, at a minimum, it is obligated to investigate further and resolve the red flags, or, if it chooses not to investigate and resolve, it must report the order as suspicious to DEA and not ship the controlled substances. *See infra*, section IV.A.4.

D. Pro Compliance and Market Basket Reports

In conducting customer due diligence, Respondent used, at least up to and including during the hearing, Pro Compliance Reports,[20] which provide analysis of a pharmacy's dispensing data to include key indicators of red flags of diversion, such as the percentage of a customer's business that represents controlled substance dispensing, the volume of cash payments, and the amount of trinity drug cocktails filled. Tr. 464-65, 716-17. In this case, the reports in Respondent's possession for the exemplar pharmacies demonstrated numerous red flags of diversion, and the Agency finds substantial record evidence that Respondent did not adequately document the resolution of those red flags or report the orders to DEA as suspicious.[21] Additionally, the reports in evidence for the exemplar pharmacies appear to demonstrate violations of Respondent's purported policy of "eliminating pharmacy customers who fill orders for controlled drugs in excess of acceptable ratios, accept cash payments,

[20] Each Pro Compliance Report contains a statement regarding the Controlled Substances Act (CSA) requirement on manufacturers and distributors to design and operate a system that will disclose suspicious orders of controlled substances. *See, e.g.*, GX 23, at 11; Tr. 355.

[21] Respondent argues that "the Government offered no evidence to demonstrate that Respondent failed to dispel suspicion." ALJX 89, at 100. The Agency finds this argument to be circular. Respondent did not maintain adequate documentation of its resolution of red flags or suspicious orders, so there is no evidence to demonstrate whether it did or did not conduct the due diligence necessary to resolve the red flags. *See infra* n.80. As described herein, the Agency requires documentation of Respondent's due diligence for many reasons.

prescribe the 'Holy Trinity' and/or other unacceptable practices." GX 9, at 1. According to Respondent, Market Basket Reports[22] were prepared for each customer on a monthly basis as part of its due diligence. GX 9, at 3-4. The reports identified percentages of controlled substances in total dispensing. *Id.*; *see, e.g.*, GX 59. Respondent no longer uses Market Basket reports but continues to use Pro Compliance Reports. Tr. 716.

The GS testified that he did not find evidence that Respondent ever rejected a controlled substance order from any of the exemplar pharmacies, nor did he find documentation that Respondent dispelled all of the red flags in these reports. Tr. 385-86, 316,[23] 413.

1. Folse Pharmacy

The record evidence demonstrates that the Pro Compliance Initial Risk Evaluation Report provided to Respondent for Folse Pharmacy designated the pharmacy as "high risk." GX 22, at 5; Tr. 328. Further, Pro Compliance Reports for Folse Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Folse Pharmacy's dispensing practices raised numerous red flags, including: high percentages[24] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[25] an

[22] Respondent points out that the GS's testimony regarding the Market Basket reports was possibly based on a misinterpretation of the numbers. ALJX 89, at 30 (citing Tr. 409, 423-425). In adjudicating the allegations, this Decision focuses on the Pro Compliance Reports in which there is more than enough information to support the Agency's finding that the alleged customers presented red flags of diversion, the resolution of which was not adequately documented, yet Respondent continued to ship. The Market Basket Reports are only considered to demonstrate that Respondent was conducting some due diligence.

[23] Respondent points to Irelan's testimony to contest the notion that Respondent was not stopping shipments based on reports; however, the citations to his testimony support that Respondent was generally conducting some due diligence as it had described in its letters to DEA in response to the subpoena, not that the red flags at issue for the exemplar pharmacies were resolved. ALJX 89, at 16; *see also, e.g.*, RX 31.001 (notes on pharmacies other than exemplar).

[24] According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 30 to 36 percent of Folse's total dispensing. GX 22, at 12-17.

[25] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 18 to 41 percent. GX 22, at 12-14, 17.

increase[26] in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.[27] *See* RD, at 51-53. Furthermore, in June 2017, a Pro Compliance Report recommended that Respondent engage with Folse's owner to "gain a better understanding of [its] dispensing practices . . . ." GX 22, at 17. The record does not include evidence of an investigation into or resolution of the red flags identified. Further, the record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 340; Stip. 13.

2. Bordelon's

Pro Compliance Reports for Bordelon's Super Save Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Bordelon's dispensing practices raised numerous red flags, including: high percentages[28] of controlled substance prescriptions, higher than average oxycodone and hydrocodone units, and dispensing of trinity cocktail prescriptions.[29] *See* RD, at 53-54. In March 2017, a Pro Compliance Report recommended that Respondent engage with Bordelon's owner to "gain a better understanding of [its] dispensing practices . . . ." GX 21, at 6. The record is clear that Respondent did not report any orders from this customer to DEA as suspicious and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 347-48; Stip. 12.

3. Wallace Drug Company

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[26] Between September 2013 and November 2014, the number of oxycodone dosage units dispensed increased from 40,812 to 52,571. GX 22, at 12; Tr. 330-31 (The GS describing this increase as "a very big red flag"); *see also* Tr. 471-74.

[27] In June 2017, Folse dispensed nine trinity drug cocktails and in September 2016, Folse dispensed twenty-two trinity drug cocktails. GX 22, at 17, 14; Tr. 300, 335-36.

[28] In March 2017, the percentage of controlled substances dispensed represented 17 percent of Bordelon's total dispensing, which Pro Compliance reported to be "slightly higher than national averages." GX 21, at 5-6.

[29] In March 2017, Bordelon's dispensed four trinity drug cocktails. GX 20, at 5-6.

Pro Compliance Reports for Wallace in Respondent's possession demonstrated that during the time period of the allegations, Wallace's dispensing practices raised numerous red flags, including, but not limited to: high percentages of controlled substance prescriptions paid for in cash,[30] higher than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.[31] *See* RD, at 54-55. In August 2017, a Pro Compliance Report recommended that Respondent engage with Wallace's owner to "gain a better understanding of [its] dispensing practices." GX 20, at 6. Respondent produced phone log entries on January 9, 2018, for Wallace. *See* GX 14, at 31 (note stating that the pharmacy salesman had been contacted and Respondent recommended that he return the order, noting "might need to check on this guy" and "looks like he is hitting this stuff hard!"). Another note on the same date states that the customer was contacted and the customer explained the large order. According to the note, Respondent's employee recommended the return of the hydrocodone and the customer returned it. This note did not occur until five months after the Pro Compliance Report for Wallace, which demonstrated multiple additional red flags of diversion for which there is no documented resolution. Therefore, it is unclear whether the employee flagging this particular order knew that there might be further reason to suspect that this pharmacy was engaging in diversion in order to be able to adequately resolve the suspicious circumstances surrounding the order. Even if this note arguably provided a documented resolution of an unusually large order, the other red flags for this customer are unresolved and unaccounted for. There is also no record evidence that Respondent reported the unusually large order or any orders from this customer to DEA and

[30] In August 2017, 31 percent of controlled substance prescriptions filled by Wallace were paid for in cash. GX 20, at 5.

[31] In August 2017, Wallace dispensed three trinity drug cocktails. GX 20, at 5-6; Tr. 349-50.

there is no record evidence that Respondent stopped shipping to this customer as a result of these reports or notes. Tr. 353; Stip. 11.

4. Pharmacy Specialties Group

Pro Compliance Reports for Pharmacy Specialties in Respondent's possession demonstrated that during the time period of the allegations, Pharmacy Specialties' dispensing practices raised numerous red flags, including: high percentages[32] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[33] an increase[34] in the number of hydrocodone, oxycodone, and benzodiazepine dosage units dispensed, and dispensing of trinity cocktail prescriptions.[35] *See* RD, at 55-57. In February 2016, a Pro Compliance Report recommended that Respondent engage with Pharmacy Specialties' owner to "gain a better understanding of [its] dispensing practices." GX 23, at 6. Respondent's phone logs demonstrate that an employee raised a concern on March 7, 2016, regarding Pharmacy Specialties Group; however, there is no record documentation of how the concern was resolved and Respondent continued to distribute. *See* GX 14, at 4 ("[C]heck out this guys usage for item [] compared to his overall warehouse purchasing, this seems quite elevated to me.....????"). This note identifies a suspicious order; however, according to the record evidence, Respondent did not report the order to DEA. Further, there is no documented investigation or resolution of the concern raised by the employee in the record. On December 13, 2017, another note reads, "Henry will give the customer a warning about his Oxy purchases.

[32] According to the Pro Compliance Reports in evidence, the percentages of controlled substances ranged from approximately 24 to 30 percent of Pharmacy Specialties' total dispensing. GX 23, at 5, 18; Tr. 353-54.
[33] According to the Pro Compliance Reports in evidence, the percentages of controlled substances dispensing paid for in cash ranged from approximately 28 percent to 31 percent. GX 23, at 5-6, 16, 18, 18.
[34] From February 2016 to October 2016, the number of hydrocodone dosage units dispensed increased by 25 percent, while from October 2016 to September 2017, the number of dosage units of oxycodone, hydrocodone, and benzodiazepines dispensed increased by 148, 89, and 106 percent respectively. GX 23, at 16, 18; Tr. 358-59.
[35] In February 2016, October 2016, and September 2017, Pharmacy Specialties dispensed trinity drug cocktails. GX 23, at 6, 16; Tr. 355, 358-59.

Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely." *Id.* at 31. Although this note seems to set forth a plan for compliance, it does not include any indication of an investigation into or resolution of the red flags identified. Further, the record evidence is clear that Respondent did not report this order or any orders from this customer to DEA and there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 362; Stip. 14.

5. Dave's Pharmacy

Pro Compliance Reports for Dave's Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Dave's dispensing practices raised numerous red flags, including: high percentages[36] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[37] increases[38] in the number of oxycodone dosage units dispensed, and dispensing of trinity cocktail prescriptions.[39] *See* RD, at 57-59. In March 2014, a Pro Compliance Report recommended that Respondent engage with Dave's owner to "gain a better understanding of [its] dispensing practices. . . ."[40] GX 24, at 6. It also states that this pharmacy "represents a relatively ***high risk*** to [Respondent]." *Id.* (emphasis in original). A year later, on February 16, 2017, Respondent's phone logs contain the following

[36] According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 20 to 22 percent of Dave's total dispensing. GX 24, at 5, 18-21, 24, 30; Tr. 362-67.

[37] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 35 percent. GX 24, at 18-21, 23, 24, 30; Tr. 364-67.

[38] For example, from March 2014 to January 2015, the number of oxycodone dosage units dispensed increased from 17,889 to 29,994, and from May 2014 compared to December 2015, the number of dosage units of oxycodone increased by 205 percent. GX 24, at 18, 19, 21; Tr. 364; *see also* RD, at 57-59.

[39] Between March 2014 and January 2015, Dave's dispensed 57 trinity drug cocktails. GX 24, at 18; Tr. 364. Between May 2014 and December 2015, Dave's dispensed 27 trinity drug cocktails, and between December 2015 and June 2016, Dave's dispensed 33 trinity drug cocktails. GX 24, at 19-20. Tr. 365-66. Further, between June and November 2016, Dave's dispensed 37 trinity drug cocktails and in June 2017, Dave's dispensed 14. GX 24, at 21, 24.

[40] This Pro Compliance Report identifies Dave's second highest prescriber as having eighty-five incidents of prescribing trinity drug cocktails.

note about Dave's: "Talked to [D.J.] about the issues at his store. He will let the doctors know that he will no longer be filling these scripts." GX 14, at 23. According to the record evidence, Respondent did not elicit or document an explanation for the red flags and the record is clear that Respondent never reported this order or any orders from this customer to DEA. Further, there is no record evidence that Respondent stopped shipping to this customer as a result of these reports. Tr. 384-85; Stip. 15.

6. Hephzibah Pharmacy

A Pro Compliance Report for Hephzibah Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Hephzibah's dispensing practices raised numerous red flags, including: high percentages[41] of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash,[42] and dispensing of trinity cocktail prescriptions.[43] *See* RD, at 59-60. In February 2017, a Pro Compliance Report recommended that Respondent engage with Hephzibah's owner to "gain a better understanding of [its] dispensing practices. . . ." GX 25, at 6.

Jacob Dickson sent an email to a DI stating that Respondent had ceased business with Hephzibah because Respondent did not support the customers who "wished to change their business model;" however, Respondent "did not find these accounts to exhibit suspicious activity or excessive orders." GX 72, at 1. Respondent's phone logs state on March 17, 2017, that "they must work on clearing up issues that Pro Compliance found, high cash, trinity & high quantities on Hydrocodone and Oxycodone. Will re-run in 90 days." GX 14, at 23. On March 21, 2017,

[41] In February 2017, controlled substance prescriptions constituted 27 percent of Hephzibah's total dispensing. GX 25, at 6; Tr. 370-71.
[42] In February 2017, the percentage of controlled substance dispensing paid for in cash was 36 percent. GX 25, at 6, 12; Tr. 371.
[43] In February 2017, Hephzibah dispensed nine trinity drug cocktails. GX 25, at 5-6; Tr. 371.

there is a follow up entry that states, "After a couple of months, they decided they would rather change wholesalers than cooperate with our compliance program." *Id.* at 26. Although the notes demonstrate that Respondent was conducting some due diligence, this statement contradicts Jacob Dickson's email asserting that Respondent terminated the business relationship and also that Respondent did not find the accounts to exhibit suspicious activity when it clearly had identified red flags through Pro Compliance Reports. *See* GX 72, at 1 (listing Hephzibah Pharmacy as an account that Respondent "chose to close").[44]

7. The Wellness Pharmacy

Pro Compliance Reports for the Wellness Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wellness's dispensing practices raised red flags of very high percentages of controlled substance prescriptions and high numbers of dosage units of hydrocodone and oxycodone. *See* RD, at 60-61. Although Pro Compliance's initial risk assessment evaluated Wellness as "low risk," it also revealed that between April and June 2013, 67 percent of all prescriptions dispensed by Wellness were for controlled substances. Further Pro Compliance Reports during the relevant time period demonstrated that Wellness's percentage of controlled substance prescriptions continued to range from approximately 64 to 69 percent. GX 26, at 10-12, 14, 21; Tr. 374. There is no record evidence that Respondent reported these orders to DEA or any orders from this pharmacy, documented the resolution of the red flags, or stopped shipping to this customer as a result of the red flags that these reports identified. Tr. 384-85; Stip. 17.

8. Wilkinson Family Pharmacy

[44] The Agency agrees with the ALJ's finding that the phone log note deserves more weight as to what occurred with this pharmacy than Jacob Dickson's email. RD, at 136 n.60.

Pro Compliance Reports for Wilkinson Family Pharmacy in Respondent's possession demonstrated that during the time period of the allegations, Wilkinson's dispensing practices raised numerous red flags, including: high percentages[45] of controlled substance prescriptions, increases in oxycodone, high percentages of controlled substance prescriptions paid for in cash,[46] higher than average dosages of oxycodone and hydrocodone, and dispensing of trinity cocktail prescriptions.[47] *See* RD, at 61-63. In January 2017, a Pro Compliance Report recommended that Respondent engage with Wilkinson's owner to "gain a better understanding of [its] dispensing practices." GX 27, at 26.[48] There is no record evidence that Respondent reported these orders or any orders from this customer to DEA, or stopped shipping to this customer as a result of these reports. Tr. 384-85; Stip. 19.

The Government has presented substantial record evidence that Respondent distributed controlled substances to the exemplar pharmacies during the relevant time period in the face of

[45]According to the Pro Compliance Reports in evidence, percentages of controlled substances during the relevant time period ranged from approximately 9 to 42 percent of Wilkinson's total dispensing. GX 27, at 20-23. 25-26; Tr. 367, 378-380.

[46] According to the Pro Compliance Reports in evidence, percentages of controlled substance dispensing paid for in cash ranged from approximately 17 to 38 percent and cash paid for non-controlled substance prescriptions was significantly lower. GX 27, at 20-23; Tr. 378-380.

[47] Between March 2014 and January 2015, Wilkinson dispensed twenty-six trinity drug cocktails. GX 27, at 21; Tr. 378. Between January 2015 and January 2016, Wilkinson dispensed twenty-one trinity drug cocktails, and between December January 2016, and August 2016, Wilkinson dispensed twenty trinity drug cocktails. GX 27, at 22-23. Tr. 379. Further, in January 2017, Wilkinson dispensed fourteen trinity drug cocktails, and in June 2017, Wilkinson dispensed 14. GX 27, at 26, 32.

[48] Respondent produced an email from March 4, 2014, from Wilkinson, which appeared to be in response to a Pro Compliance Report that Respondent had sent to Wilkinson. Wilkinson's explanation primarily focuses on cash payments. RX 05.001. The GS testified that this showed "some" due diligence. Tr. 452. There was extensive dispute about the introduction of this exhibit during the hearing. Tr. 453-458. It appeared that Respondent did try to offer the exhibit into evidence, Tr. 453, and then offered it subject to connection. Tr. 455. The ALJ ultimately determined to send it to the Agency as part of the administrative record. RD, at 104 n.41. The Agency has considered this exhibit because the contested nature of the hearing at this point has made it difficult to determine whether this exhibit was offered. The exhibit demonstrates that Respondent conducted "some" due diligence on Wilkinson. However, it is noted that the document does not demonstrate the resolution of each of the red flags of diversion, nor does it reflect any independent analysis of Respondent's statements regarding the cash red flag. Ultimately, the Agency accepts that Respondent conducted "some" due diligence for Wilkinson. Further, even if Respondent had adequately resolved the red flags for this pharmacy, there is more than enough evidence of Respondent's failures to conduct due diligence to support the Agency's finding that Respondent's registrations are inconsistent with the public interest.

red flags of diversion, including high percentages of controlled substance prescriptions, high percentages of controlled substance prescriptions paid for in cash, dispensing of trinity cocktail prescriptions, and increases and higher than average dosages of particular schedule II controlled substances. All of these red flags were specifically identified by Pro Compliance Reports in Respondent's possession. Although some of the notations provided by Respondent demonstrated that employees had suspicions about certain orders and had made some contacts, none of the notations adequately resolved the red flags and none of the orders were reported to DEA as suspicious. In the documents Respondent produced to DEA, the GS did not find any indication that the Compliance officer stopped shipment of any order of controlled substances identified as suspicious. Tr. 315-16, 385. It is noted that most of these customers displayed not just one red flag, but multiple red flags of diversion—most of them well over any arguable threshold that would require investigation, *see supra* notes 15-16—and there is insufficient record evidence that Respondent conducted or documented due diligence to resolve these numerous red flags of diversion presented by its customers.

E. Suspicious Orders under 21 C.F.R. § 1301.74(b)

The Government alleged that Respondent failed to design and operate an effective system to disclose to Respondent suspicious orders and to report those orders to DEA. OSC, at 8. DEA used statistical analysis of orders placed by Respondent's customers for oxycodone and hydrocodone to "identify extremely large individual pharmacy transactions and extremely large monthly volume totals," in order to demonstrate the failures of Respondent's SOM system and reporting. *Id.* The GS explained that the reporting of suspicious orders is particularly important for DEA to be able to "conduct an investigation" and identify potential diversion. Tr. 284-86.

G.R. testified regarding the statistical analysis that he performed for the investigation, including his use of a statistical methodology called the Tukey method to identify outlier transactions that represented possible suspicious orders. Tr. 225; 236-37. G.R. testified that Tukey uses an interquartile range, which is the difference between the first and third quartiles, and then is multiplied by a factor of one-and-a-half to six (IQR multiplier). Tr. 202. Although there is no single multiplier to use, Tr. 523, the higher the IQR multiplier, the fewer outliers will be identified. Tr. 523-24. G.R. used an IQR multiplier of 3 to calculate a smaller group of outliers to identify "what are called far out or extreme outliers." Tr. 203, 233, 242. G.R. testified that the transactions that he identified using three IQR above the 75th percentile represented unusually large transactions, which would normally occur less than one percent of the time. Tr. 238-39.

G.R. testified that he analyzed Respondent's sales of oxycodone and hydrocodone from January 1, 2014, to April 30, 2018, and compared every transaction the pharmacy made from January 1, 2014, to April 30, 2018, against every other transaction made during the same time period to the same pharmacy, which he called a "fixed-frame analysis." Tr. 197-98; 226-27. He credibly testified that he used the fixed-frame analysis because he was looking for "a ballpark estimate of scale, size of outlier population," as opposed to the exact number of outliers. Tr. 227, 234.

Government Exhibits 65 and 66 contain all of the transactions concerning oxycodone shipments that Respondent reported to DEA between January 1, 2014, and April 30, 2018, as well as the results of G.R.'s corrected analysis using the above-described methodology. Tr. 71-72. GX 65, 66; Tr. 71-72, 211-12. G.R.'s corrected analysis identified the following amounts of

Respondent's oxycodone and hydrocodone sales as outliers, i.e., unusually large, from January 1, 2014, to April 30, 2018.

Substance	2014	2015	2016	2017	2018[49]	Total
Oxycodone	2,097	1,857	1,546	1,361	391	7,252
Hydrocodone	1,919	1,314	1,006	536	173	4,948

Tr. 212-13; GX 65-66, at Summary tab; Government Demonstrative Exhibit (GDX), at 10.

G.R.'s corrected analysis also identified approximately 450 potential outliers for Respondent's oxycodone and hydrocodone sales for seven[50] of the exemplar pharmacies from January 1, 2014, to April 30, 2018. Tr. 213-14, 216-17, 243; GDX, at 11.[51] *See* RD, at 68 for table. The Agency is considering the review of the exemplar pharmacies' unusually large orders for oxycodone and hydrocodone only to further demonstrate the general failure of Respondent to identify, investigate and report suspicious orders.[52]

In response to criticism from Respondent's expert, G.R. also conducted a "look-back analysis," which, according to G.R., produced results "consistent with what [he] found using the"[53] fixed-frame analysis method. Tr. 228, 235. In his look-back analysis, G.R. looked at "the entire population" and not only the seven exemplar pharmacies in the OSC showing unusually

[49] January 1, 2018, to April 30, 2018. Tr. 212, 226.
[50] G.R.'s corrected analysis did not identify any unusually large transactions of oxycodone or hydrocodone that Respondent shipped to Hephzibah Pharmacy. ALJX 14, at 4; Tr. 230. However, the Pro Compliance Report for Hephzibah Pharmacy demonstrated multiple red flags of diversion. *Supra* section III.D.6.
[51] The tables reflect transaction size, not frequency. Tr. 244.
[52] It is noted that Weinstein conducted a "look-back" analysis of G.R.'s data; Tr. 537-38, 550-51, 693, RDX-4; *see also* RD, at 73 (table analyzing these amounts). The Agency acknowledges that Respondent demonstrated Weinstein's analysis produced significantly lower results; "nearly half of the outlier transactions he identified in 2017 and 2018 would not have been identified as outliers." ALJX 89, at 38 (citing Tr. 529-30, 568; RX 28 and 29)).
[53] Respondent argued in its Exceptions that G.R.'s look-back analysis could not be characterized as "substantially similar" to the fixed-frame analysis because although the numerical size of outliers was similar, each analysis found substantially different outliers. Resp Exceptions, at 41-42. Respondent's point is noted; however, both analyses identified numerous outliers and, ultimately, the number of outliers that could have represented suspicious orders under both analyses far exceeded the three that Respondent reported to DEA during the relevant timeframe. Further, Respondent did not demonstrate adequate documentation of its resolution of suspicious orders nor is there information on the record that Respondent stopped shipping.

large transactions. Tr. 230. G.R. testified that statistical analysis is "one piece of the analysis that is necessary to comply with DEA's regulations governing distributors." Tr. 223-24, 1084-90. *See* GX 73 and 74 (analysis using the look-back methodology that Weinstein recommended). The look-back analysis for oxycodone transactions revealed 6,816 outlier transactions, a 6 percent reduction when compared to the fixed-frame analysis of 7,252 that the Government previously found. Tr. 1091; GX 73, at Summary tab. The look-back analysis for hydrocodone transactions revealed 5,222 outlier transactions, a 5.5 percent increase when compared to the fixed-frame analysis of 4,948 that the Government previously found. Tr. 1092; GX 74, at Summary tab.[54]

Respondent presented the testimony of its own expert, Weinstein, who opined that G.R.'s analysis failed to reliably identify unusually large or suspicious orders. Tr. 558. Weinstein based his criticism of G.R.'s analysis on four factors: 1) the use of a four-year fixed-frame as opposed to the look-back method; 2) the failure to consider the schedule change of hydrocodone in late 2014 from schedule III to schedule II; 3) the failure to consider package size and formulation; and 4) the use of the line item approach as opposed to a cumulative approach. RD, at 70; Tr. 525-28, 541-46, 558.

Weinstein credibly explained his criticisms of G.R.'s analysis in detail, opining that the factors he identified both over-estimated, *see, e.g.*, Tr. 552, and under-estimated, *see, e.g.*, Tr. 552-53, the number of outliers that could have potentially constituted suspicious orders.

[54] Respondent contests the Government's introduction of this rebuttal evidence in its Exceptions. Resp Exceptions, at 40-41. As further explained herein, the Agency credits Weinstein's criticism of G.R.'s analysis. The exact number of unreported suspicious orders is unnecessary for the Government to prove or the Agency to conclude in finding a violation because Respondent was responsible for creating and maintaining an adequate SOM system and identifying and reporting suspicious orders. Here, it is clear from the evidence that Respondent's SOM system during the relevant timeframe was inadequate.

Weinstein notably "did not conduct an original analysis to determine, retrospectively, which of Respondent's orders from 2014 through 2018 should have been identified as suspicious." Resp Exceptions, at 40; *see also* RD, at 25, 75. Respondent argues that it is not Respondent's burden to do so. Resp Exceptions, at 40 (citing *Steadman v. Securities and Exchange Comm'n*, 450 U.S. 91, 100-03 (1981); *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; 21 C.F.R. § 130.44(e)).

Even if the Agency fully credits Weinstein's criticism of G.R.'s analysis, the Government has clearly demonstrated its *prima facie* case that Respondent failed to design and operate a system to identify suspicious orders and report them to DEA and Respondent admits as much. *See, e.g.*, Tr. 666 (Weinstein testifying that the numbers run in early 2018 would have identified suspicious orders in similar quantities to what Respondent is currently reporting); Tr. 813 (Irelan testifying that he accepts responsibility for the Government's allegations in the OSC, paragraph 10, regarding the failure to design and operate an adequate SOM system). The G.R. analysis, according to G.R.'s credible testimony, offered a ballpark estimate of the scale of suspicious orders that Respondent neglected to identify and report to DEA. RD, at 12, and 136; *accord* Tr. 404 (The GS testifying that he asked G.R. to conduct an analysis "to get a sense of just mathematically quantifying how many suspicious orders could theoretically have been missed by Morris & Dickson"[55]). Respondent argued that the Government's case was founded[56] on

[55] It is noted that Respondent uses a different quote from the GS that stated that the intent of the analysis was "to quantify, you know, just how many orders are we talking about that fell outside of just a normal pattern or set amount" and that "the analysis showed that there were roughly, 14,000 orders that should have been reported as suspicious based on the quantity that was ordered." Respondent's Exceptions, at 45 (quoting Tr. 293). Given the several contextual parameters that the GS used in these statements, like "just a normal pattern or set amount" and "based on the quantity that was ordered," the Agency does not find this statement to be inconsistent with the GS's statement at Tr. 404, regarding the purpose of G.R.'s analysis.

[56] The Government's Prehearing Statement states that G.R. "will testify that a standard statistical outlier analysis is a reasonable method to identify unusual transactions in the context of pharmaceutical distribution." ALJX 7, at 6. The description of G.R.'s testimony in both the Government's Prehearing Statement and Third Supplemental Prehearing

establishing specific outliers that Respondent failed report to DEA as suspicious orders. Resp Exceptions, at 43 (citing *e.g.*, OSC, at 37, 46, 54, 65, 74, 84, 93); *see also* ALJX 52, at 20. However, the Agency does not find it necessary to count and identify the exact number of specific outliers, and the reason why is simple. Respondent is charged with violating a non-prescriptive regulation, which clearly places the burden on the distributor to design and operate a system to disclose to the distributor suspicious orders of controlled substances under Agency guidelines.[57] The DEA regulations notably do not prescribe *exactly* what SOM system to use or what constitutes a suspicious order—what constitutes an order of unusual size, an order deviating substantially from a normal pattern, etc. Respondent, in its defense, did not attempt to demonstrate that the system that it had in place during the relevant time period adequately identified suspicious orders—in fact, Irelan took responsibility for Respondent's SOM system failures and failure to adequately report suspicious orders to DEA. Tr. 731, 733. Based on the evidence in the record and Respondent's admitted failures, the Agency finds that Respondent clearly violated 21 C.F.R. § 1301.74(b) in failing to design and operate its system and in failing to investigate or report suspicious orders to DEA. Respondent's attempts to distract the Agency from the notion that it did not adequately meet the regulatory obligation by picking apart DEA's ballpark estimate demonstrating the potential magnitude of Respondent's violations are unavailing. The Agency notes that Respondent contests the quantity of suspicious orders that G.R. identified as unreported to DEA; but G.R.'s analysis, which he notably calibrated to only

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Statement discusses the manner in which G.R. arrived at his calculations and established reasonable thresholds. *Id.* at 6-8; ALJX 52, at 20 ("G.R. will testify that his analysis identified the following unusually large transactions for the exemplar pharmacies."). The Agency additionally agrees with the rationale of the ALJ that G.R.'s testimony regarding the intent of his statistical analysis did not give rise to a new allegation. *See* RD, at 96 n.33.

[57] The December 20, 2007 letter that DEA sent to manufacturers and distributors stated that "[t]he regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders." GX 4, at 1.

identify extreme outliers, Tr. 203, shows that the number of unreported suspicious orders for these two controlled substances during the relevant timeframe could have potentially been in the thousands.[58]

F. Respondent's Policies and Procedures During the Relevant Timeframe

Respondent produced a Policies and Procedure Manual and a Standard Operating Procedures (SOP) Manual in response to DEA's investigation. GX 17 and 18. The Policies and Procedure Manual states, "Where a Compliance Officer sees a ratio of controlled drugs ordered out of the normal range, or the overall quantity is too high compared with the volume of the account, the Compliance Officer has a duty to investigate by calling the account. The Compliance Officer may stop shipment on any order if he or she finds the order to be unusually suspicious." GX 17, at 12. The Policies and Procedures Manual notably does not indicate an obligation to report suspicious orders to DEA. The GS testified that in his review of Respondent's records, he did not see documentation of stopped suspicious orders. Tr. 315-16. The SOP Manual[59] states that Respondent "keeps a system in operation which is designed to discover those purchasing patterns of controlled substances which exceed the norm and could possibly be related to diversion activities." GX 18, at 19. The GS testified that this statement does not adequately reflect the obligations in 21 C.F.R. § 1301.74(b). Tr. 307. Further, although the SOP Manual describes various analytical reports regarding drug sales and drug volumes, the GS testified that he did not see any references to these reports in Respondent's relevant records. Tr. 308-09, 491. The SOP Manual does clearly state that "[w]hen a suspicious pattern or

[58] Respondent further made arguments related to what it determined as inconsistent analysis in the RD related to G.R.'s outlier numbers. Resp Exceptions, at 44-46. The Agency finds that G.R.'s analysis provides a ballpark of the egregiousness of Respondent's failures to design and operate the required system. *See* Tr. 227, 224.
[59] The SOP Manual states that the details of Respondent's suspicious order monitoring program "are confidential and therefore are not made a part of this manual." Tr. 306; GX 18, at 17.

purchase is identified by any of the above methods the customer is contacted in some but not all cases and asked for a written explanation for the unusual order. In all cases,[60] a letter is sent to the DEA indicating a possible suspicious order." GX 18, at 20.

G. Respondent's Former SOM System

Irelan testified that Respondent's SOM system during the time period comprising the allegations (former SOM System) was "not as robust as what we have today." Tr. 738-40 (citing *e.g.*, GX 19, at 3); *see also* RX 31.001 and 31.002 (notes that were part of Respondent's former SOM System). The former SOM system included: know your customer efforts; an electronic customer profile (ECP); a market basket system; reports from Pro Compliance; direct contact with and soliciting of information from customers; and reliance on Respondent's sales force and those who actually filled orders for controlled substances. Tr. 866-70; GX 9, at 2-3; GX 17, at 12; GX 18, at 19-20.

Irelan testified that Respondent's former SOM system would send an email or text message to the compliance officer, C.G., when an order was flagged as suspicious and the order would ship if C.G. did not take action to stop it. Tr. 728, 778.

Irelan testified that Respondent's former SOM system was "not consistent with best practices . . . . because it didn't hold the order. It didn't give an opportunity to resolve red flags before shipping." Tr. 729. Additionally, Irelan testified that "the calculation that the system was using [to identify potentially suspicious orders] was only using ten times a 90-day average," which made it "inadequate." Tr. 729; *see also* Tr. 321-22 (The GS testimony that 8 times the

[60] The GS testified that customers should be contacted in all cases. Tr. 484. *Masters* may provide some room for nuance if Respondent stops shipment of the orders and reports to DEA; however, none of this nuance is represented in the SOP Manual. Additionally, the policy states that "in all cases," DEA is required to be notified, when in fact, DEA was only notified three times during the relevant time period and the record evidence established that Respondent neither reported to DEA nor adequately documented the resolution of red flags for the exemplar pharmacies or generally for suspicious orders during the relevant time period. *See supra* III.D.

average could still be a suspicious order); Tr. 652 (Weinstein testifying that this calculation was not sufficient based on DEA guidance). Regarding the former SOM system, Milione testified that his "understanding is they accepted that there were things wrong with it, that the reporting to DEA was insufficient." Tr. 989. Further, he stated, "it was clear that there was an issue" and that after reviewing the system, his company told Respondent that "there are certain things that should be enhanced knowing what DEA expected." Tr. 990-91. For example, "one of the big things was a way to flag orders [in] real time and in an appropriate way with some kind of an algorithm and then report those flagged orders to DEA." Tr. 991.

Respondent also argues that as a result of its former SOM system, it had ceased supplying controlled substances to 42 pharmacies from 2014 to 2016. RX 11, at 14 (powerpoint slide); Tr. 871. Respondent's expert acknowledged that if those customers had been terminated based on Respondent's SOM program, it should have filed suspicious order reports with DEA. Tr. 1015-16; *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (holding that a distributor discovering a suspicious order must either stop shipping and report to DEA or investigate and resolve the red flags). If Respondent stopped shipping and terminated a customer as a result of discovering a suspicious order, that order should have been reported to DEA. There is no evidence that the 42 customers from 2014 to 2016 were reported to DEA—in fact, the evidence establishes that there was only one suspicious order report filed during this timeframe on April 7, 2014. *See* GX 6, at 1.[61]

[61] It is also noted that Jacob Dickson's letter stated that Respondent had ceased supplying 142 retail pharmacies "due to questions and concerns that the pharmacies were overdispensing controlled substances. After ceasing doing business with these 'bad accounts' [Respondent] has seen very few examples which would justify the reporting of a suspicious order." GX 9, at 5. Milione testified that Mr. Dickson "specifically took pride in being able to say, look, this—every year there has been this—this many customers that they focused on and identified. And I think—I don't know the exact math. It was 125, 135 customers from 2008 to 2016 that were terminated or suspended . . . based upon their compliance suspicious order monitoring program." Tr. 870-71. Respondent provided transcribed testimony from Mr. Dickson in a separate hearing stating that Respondent eliminated 142 customers "because in

H. Respondent's New SOM System

Respondent requested confidentiality related to its current SOM system and policies; therefore, this Decision incorporates by reference the findings of the RD related to Respondent's system and summarizes herein at as high a level as possible while appropriately adjudicating the facts.[62] *See* RD, at 75-82. Guidepost[63] undertook seven corrective measures on Respondent's behalf. Tr. 882. Those measures included: (1) establishing an anti-diversion compliance regulatory affairs team; (2) enhancing Respondent's SOM system; (3) redeveloping Respondent's ECP; (4) enhancing Respondent's "know your customer protocols"; (5) enhancing Respondent's due diligence investigative protocols; (6) conducting employee training; and (7) documenting everything and reporting to DEA. Tr. 882-900. The Analysis Group, Inc., (AGI) was also brought in to develop a live real-time order monitoring system that would identify suspicious orders. Tr. 885. Between May 14, 2018, and July 29, 2018, Respondent submitted 58 suspicious order reports to the DEA. RX 20. In those 58 reports, Respondent informed the DEA

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some form or fashion they might have been suspicious and diverting." RX 1, at 61. It is unclear how many of these customers were terminated during the relevant timeframe—other than the 42 customers that were terminated during 2014 to 2016. Without the benefit of evidence or testimony regarding the circumstances of the terminations during the relevant timeframe, it is difficult for the Agency to determine what weight to give these terminations, *see* RD, at n.32; however, the language on the record describing these orders as "suspicious and diverting" or "overdispensing" or "bad accounts" certainly brings into question whether they could constitute additional violations of the suspicious order reporting requirement. *See also* RD, at 136. In sum, without further evidence explaining the circumstances of the terminations or the reasons why they were unreported to DEA, the Agency cannot give Respondent's terminations during the relevant timeframe the weight that Respondent requests to demonstrate its compliance. These terminations are not being considered as further violations of DEA regulations, but they are also not given weight for Respondent in the public interest inquiry. Finally, the Agency notes that whether Respondent's SOM System was adequate prior to the relevant timeframe is not a matter currently before the Agency.

[62] *See, e.g.*, Tr. 15 (Respondent requesting confidentiality based on "proprietary trade secrets of the Analysis Group regarding the customized suspicious order monitoring system that they have developed for the Respondent, as well as all of the different functionality of the Respondent's suspicious order monitoring system."); ALJX 82. The Agency has provided a high-level summary of these improvements to demonstrate consideration of the scope of Respondent's remedial measures. The numbers of suspicious orders have been included because the Agency finds this information to be relevant to the adjudication of this matter.

[63] Respondent paid Guidepost a large sum of money between the time the OSC/ISO was issued and May 2019 to be brought into compliance with DEA regulations. Tr. 973-74, 992 (*see* RD, at 76 for further details). Milione testified that Respondent has "spared no expense" in becoming compliant with DEA regulations. Tr. 992.

of approximately 3,915 suspicious orders. *Id.* Applying Respondent's new SOM program to its orders from early 2018, Weinstein identified a similar number of suspicious orders.[64] Tr. 666, 676, 682-83. Respondent's current SOM system holds customer's orders as "potentially suspicious" and prevents the orders from being shipped until the Compliance team has reviewed. Tr. 668-69, 672; 582. Furthermore, Respondent currently documents its due diligence regarding suspicious orders in the Enhanced Customer Profiles in a readily-retrievable format. Tr. 737, 716; RD, at 79.

IV. ANALYSIS

A distributor's registration may be suspended or revoked upon a finding that the distributor "has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section . . . ." 21 U.S.C. § 824(a)(4). With regard to distributors of schedule II controlled substances, Congress has set forth five factors to consider when determining whether the distributor's registration would be in the public interest. The factors to be considered are:

> (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
> (2) compliance with applicable State and local law;
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
> (4) past experience in the distribution of controlled substances; and

[64] Although Respondent did not run its new system on the old data during the time period covered by the OSC, Tr. 682, 686, Weinstein did testify that Respondent applied its current SOM system to the orders Respondent received in early 2018 (covering some of the allegations in the OSC) and Weinstein testified that using the current SOM system "[c]ertainly there were some that would have been identified in those months. And in a similar number to what's being identified currently." Tr. 666; *see also* Tr. 676 (data from April 2018 (in the relevant timeframe) produced a roughly similar volume of flagged orders, which "tends to be in the hundreds each month that are identified by the thresholds"). It is noted that these numbers reflect the quantity of orders that would have been flagged for suspicion and does not "take into account any due diligence" etc. Tr. 677. This testimony is not included in this Decision to prove the number of suspicious orders that DEA should have received in early 2018, but, instead, is included to further support the Agency's finding that Respondent's suspicious order monitoring and reporting during the relevant timeframe was insufficient to meet the regulatory requirements.

> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. § 823(b).[65]

The Agency considers these public interest factors in the disjunctive and may rely on any one or a combination of factors and give each factor the weight the Agency deems appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,472 (applying DEA decisions on the public interest factors in 21 U.S.C. § 823(f) to the public interest factors for distributors in 21 U.S.C. § 823(b) and (e)); *see also Southwood Pharm, Inc.*, 72 Fed. Reg. at 36,497-98. Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 Fed. Reg. 37,507, 37,508 (1993). There is no need to enter findings on each of the factors.[66] *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 482 (6th Cir. 2005); *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473.

The Government bears the initial burden of proof and must justify revocation by a preponderance of the evidence. *Steadman*, 450 U.S. at 100-03; *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; 21 C.F.R. § 1301.44(e). If the Government makes a *prima facie* case for revocation, then the burden of proof shifts to the registrant to show why its continued registration

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[65] 21 U.S.C. § 823(e) also applies to distributors of controlled substances. The section sets forth the identical factors to be considered regarding a registration to distribute controlled substances in schedules III, IV, and V, as are contained in 21 U.S.C. § 823(b) concerning schedules I and II. The Government's allegations are focused primarily on Respondent's distribution of schedule II controlled substances, but in 2014, during the time period of the allegations, hydrocodone was changed from a schedule III to a schedule II controlled substance. Tr. 539. Additionally, Respondent is a registered distributor of controlled substances in schedules II-V; therefore, the Agency, even when referring only to (b), considers the identical public interest factors under both sections 823(b) and (e) in this section.

[66] Respondent argues that "an independent consideration of each of these [five] factors [at 21 U.S.C. § 823(b)(1–5)] weigh[s] against a finding that Respondent's continued registration is inconsistent with the public interest." ALJX 89, para. 291. In other words, although the Government only submitted evidence relevant to Factor One and Factor Four, Respondent urges the Agency to find evidence relevant to all five Factors. The Agency declines to adjudicate, at Respondent's request, arguments that the Government did not make, yet notes that if it were to do as Respondent requests, the ensuing analysis of all five Factors would continue to point to the revocation of Respondent's registration.

would not be inconsistent with the public interest. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473; *see also Med. Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008).

In this case, the Government contends that Respondent's continued registrations are inconsistent with the public interest based on Factors One and Four. ALJ-90, at 27-29.

A. Respondent's Failure to Maintain Effective Controls Against Diversion and its Experience with Controlled Substances (Factors One and Four) [67]

With respect to Factor One, concerning the maintenance of effective controls against diversion, DEA has promulgated regulations to guide the regulated community. Specifically,

> All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in [21 C.F.R.] §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 C.F.R. § 1301.71(a).

DEA's security regulations further provide that:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

21 C.F.R. § 1301.74(b).

The OSC alleges that Respondent failed to maintain "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," in violation of 21 U.S.C. § 823(b)(1) and 21 C.F.R. § 1301.71(a). ALJX 1, at 3,

[67] While listing the five public interest factors of 21 U.S.C. § 823(b), the Government specifically notes that it does not rely on Factors Three or Five and makes no argument concerning Factor Two. ALJ-90, at 27-29 & n.12. Further, the Government combines its analysis of Factors One and Four. *Id.* at 28-44. The Government notes that where it has not made allegations with respect to Factors Three and Five, the factors do not weigh for or against revocation. *See* ALJX 90, at n.12. As such, although the Agency has considered all five factors, its analysis focuses on Factors One and Four.

paras. 7, 10. Second, the OSC alleges that Respondent failed to adequately "design and operate a system to disclose to the registrant suspicious orders of controlled substances" and report them to DEA, in violation of 21 C.F.R. § 1301.74(b). ALJX 1, at 3, paras. 8, 10.

Factor Four involves a registrant's past experience in the distribution of controlled substances, which the Government has argued is appropriately considered along with its maintenance of effective controls against diversion. *See, e.g., Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473. In this case, Respondent argues that its experience in the distribution of controlled substances "is extensive," as it was "founded in 1841 and distributes more than 33,000 products," and that its history of compliance weighs against a finding that Respondent's registration is inconsistent with the public interest. ALJX 89, at 115-116 (citing RX 1, at 13:16, 15:10). Although Respondent's arguments have been considered, Respondent's misconduct as described further herein precludes a finding that Respondent's experience establishes a "history of compliance." *See Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, 52,702 (2008) (analyzing the identical factor for distributors under 21 U.S.C. § 823(h)).

1. A Suspicious Order

To begin, the regulations require distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). The regulations provide that, at minimum, a suspicious order includes "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id.*; *see* section IV.A.3. These three criteria are non-exclusive and registrants may encounter other considerations beyond those spelled out in the regulation that could qualify an order as suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473-74; *Masters Pharm., Inc.*, 861 F.3d at 221 (noting the regulatory criteria for suspicion are "exemplary rather than exhaustive"). For

example, a distributor might find a pharmacy's orders for controlled substances to be suspicious not only based on their exhibiting the characteristics set forth in the regulation, but also based upon the "pharmacy's business model, dispensing patterns, or other characteristics." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,473-74; *see also id.* at 55,477 (stating that "an order is not only suspicious by virtue of its internal properties—i.e., being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order]"). The identification of a suspicious order that is based on the nature of the pharmacy's business takes place at the customer-level. *See infra* section IV.A.4.

In order to conclude that an order for controlled substances is suspicious, a "distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,480. In fact, suspicion is a low standard, defined as merely one's "'apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478 (quoting Black's Law Dictionary 1585 (9th ed. 2009)). Thus, if a distributor is aware of any indication of "the existence of something wrong" concerning the size, frequency, or pattern of an order, then the distributor is obligated to report it to the DEA. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478. Because suspicion is a low standard, a distributor's obligation to report suspicious orders is triggered long before the distributor would have probable cause to believe that a customer is engaged in diversion. *Id.* As *Masters* explains, suspicion is not contingent on evidence that the order will be diverted or that the customer is engaged in diversion. *Id.* With regard to the reporting requirement, the Agency's emphasis is on *suspicion* and not conclusive proof of diversion. *Id.* at 55,420 (explaining that tying suspicion to

evidence of diversion "imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious").

2. Respondent's Failure to Adequately Design and Operate a Suspicious Order Monitoring System.

When a distributor's suspicious order monitoring (SOM) system places a hold on a customer's order for controlled substances because the order is of unusual size, pattern, or frequency, the order meets the specific criteria of being suspicious. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,479; *Masters Pharm., Inc.*, 861 F.3d at 216-17 (affirming the Acting Administrator's ruling that "orders held by the [distributor's SOM systems] met the regulatory definition of 'suspicious orders'"). DEA has made clear that it does not endorse any particular system for identifying suspicious orders. GX 4, at 1; Tr. 59-60, 76, 210, 497, 646.

In this case, Respondent's SOM system during the relevant time period did not have the capability to hold an order that was flagged as "potentially suspicious." Tr. 728, 778. Therefore, the system could not comply with the DEA legal requirements. Tr. 729 (Irelan testifying that the SOM system was "not consistent with best practices" because "[i]t didn't give an opportunity to resolve red flags before shipping.")

Additionally, the witnesses were in agreement that Respondent's SOM system during the relevant time period was inadequate to identify orders of unusual size in that it only flagged orders that were "ten times a 90-day average," Tr. 729-30, 321, 652.[68]

Further, while Respondent had written policies and procedures, those policies and procedures only identified three suspicious orders over a period of four years and four months that were reported to the DEA. Respondent admits that its previous policies were inadequate.

[68] DEA sent a letter in December 20, 2007, warning distributors that a SOM system "rely[ing] on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders." GX 4, at 2.

Tr. 720-21. Respondent had a policy of producing monthly and daily reports, yet none is apparent in the Administrative Record, and although Respondent maintained a proprietary database, RX 11, at 5, there is no record evidence from this database.

Finally, although Respondent argues that the record supports that it was conducting due diligence into its customers, Respondent admits that it did not adequately document that due diligence, nor did it apply that due diligence at an order level. *See infra* section IV.A.4. Respondent's policy of not documenting its due diligence, GX 9, was also inconsistent with the *Masters* decision. *See id.*

In sum, the Agency finds substantial record evidence that Respondent failed to design and operate an adequate SOM system in violation of 21 C.F.R. § 1301.74(b).

3. Respondent's Failure to Report Suspicious Orders under the Listed Criteria in 21 C.F.R. § 1301.74(b)

As explained above, DEA regulations obligate distributors of controlled substances to not only design and operate a system to identify suspicious orders, but to also report all suspicious orders to DEA. 21 C.F.R. § 1301.74(b). In other words, DEA regulations require distributors like Respondent "to alert DEA when their retail-pharmacy customers *attempt* to obtain unusual amounts of a controlled substance, because such attempts are powerful evidence that the pharmacies are operating illegally." *Masters Pharm., Inc.*, 861 F.3d at 217-18 (emphasis in original).[69] Moreover, the Agency has previously held that filing ARCOS reports does not satisfy a distributor's obligation to notify DEA of suspicious orders, *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,501, nor does filing reports on a routine or periodic schedule. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478.

[69]Suspicious orders meeting the definition in 21 C.F.R. § 1301.74(b) must be reported to DEA, and Respondent did not argue otherwise. *See, e.g.*, Tr. 732, 1024; RX 20.001, at 1. There is additionally no record evidence that Respondent investigated these suspicious orders and resolved them at any time.

The purpose of the DEA's reporting requirement is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,483 n.169 (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,501). As such, when a distributor obtains "information that an order is suspicious but then chooses to ignore that information and fails to report the order," the distributor violates its regulatory obligation. *Id.* at 55,478.

Here, DEA presented evidence using the Tukey statistical model to determine a ballpark number of suspicious orders that an adequate SOM system might have identified during the time period in the allegations both for the eight exemplar pharmacies and for Respondent's customer base at large for two frequently abused controlled substances: oxycodone and hydrocodone. The ballpark estimate found numerous potential suspicious orders for seven out of the eight exemplar pharmacies, and for the overall customers, it found that 7,252 sales of oxycodone and 4,948 sales of hydrocodone during this time period should have possibly been reported as suspicious to DEA.[70]

The ballpark numbers constitute substantial evidence that there were far more suspicious orders that should have been identified, investigated, or reported than the mere three that Respondent reported during the time period. Even taking into consideration all of the criticism levied on DEA's modeling by Respondent's expert, he himself admitted that the data run during the beginning of 2018 produced similar results to the quantity that Respondent was reporting under the new system, which, in a little over a year, amounted to 3,915 suspicious orders. As such, the Agency agrees with the ALJ that the three suspicious order reports filed during the

[70] It is noted that the ballpark numbers that G.R. testified to support a conclusion that Respondent failed to identify, resolve, or report suspicious orders under the criteria in § 1301.74(b) to DEA—not whether Respondent failed to conduct customer due diligence generally.

relevant timeframe "barely scratched the surface," RD, at 140, and finds it clear that the Government has proven by substantial evidence that Respondent failed to investigate or report potentially thousands of suspicious orders of oxycodone and hydrocodone to DEA. *Supra* section III.E.

Furthermore, the *Southwood* decision explained that even *after* a suspicious order is reported to DEA, a distributor must conduct some due diligence and only ship the order "if it is able to determine that the order is not likely to be diverted into illegal channels." *Masters Pharmaceuticals*, 861 F.3d 206 (2017) (citing *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,500). Here, it is undisputed that Respondent submitted three suspicious order reports to DEA during the relevant time period. The GS testified that Respondent shipped these orders without documenting any resolution of the suspicious circumstances that caused Respondent to report them to DEA. Tr. 294. Thus, the Agency finds substantial record evidence that Respondent's lack of documentation of its investigation into and resolution of these red flags, coupled with its shipping of the suspicious orders, demonstrates additional violations of Respondent's regulatory obligations to provide effective controls and procedures to guard against diversion of controlled substances.

4. Customer Due Diligence and Red Flags

It is inherent in the obligation under 21 C.F.R. § 1301.71(a) to maintain "effective controls" against diversion that "a registrant has an affirmative duty to protect against diversion by knowing its customers and the nature of [their controlled substances] sales." *Holloway Distributing*, 72 Fed. Reg. 42,118, 42,124 (2007).[71] Therefore, a distributor is required to act on

[71] *See also Holloway Distributing*, 72 Fed. Reg. 42,118, 42,124 (2007) (finding that a distributor of List I chemicals' "policy—which is fairly characterized as 'see no evil, hear no evil'—is fundamentally inconsistent with the obligations of a DEA registrant").

"'information which raise[s] serious doubt as to the legality of [the customer's] business practices,'" also referred to as red flags,[72] indicative of diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,498). A distributor must also "conduct a reasonable investigation to determine the nature of a potential customer's business before it sells to the customer." *Id.* Furthermore, a distributor has a continuing obligation to perform due diligence of a customer throughout the distributor's relationship with that customer. *Id.* at 55,477. *Masters* clarified that "although a distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicating that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor 'inform' the Agency about the order." *Id.* at 55,478.

The record evidence and testimony from multiple experts in this case, the Pro Compliance Reports themselves, and prior DEA decisions have all clearly demonstrated that such suspicious circumstances, or red flags, include a pharmacy that: dispenses a high volume of narcotics;[73] dispenses the trinity drug cocktail;[74] dispenses disproportionally more controlled

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[72] It is noted that Agency Adjudications have used the term "red flag" as early as 1998 and federal courts have used the term as early as 1986. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,195 n.23 (2016), *pet. for rev. denied*, 881 F.3d 823 (11th Cir. 2018). In general, a red flag is any "circumstance that does or should raise a reasonable suspicion as to the validity of a prescription [or order]." *Pharmacy Doctors Enters. d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. at 10,896 n.31 (quoting *Hills Pharmacy, L.L.C.*, 81 Fed. Reg. at 49,839). Red flags are, in essence, "warning signs" or "suspicious circumstances" that alert the registrant that something is not right. *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,195 n.23.

[73] *Masters Pharm., Inc.*, 80 Fed. Reg. at 5548-81 n.168 (explaining where a distributor had information that 50 percent of the prescriptions filled by a pharmacy were for controlled substances, while the average pharmacy only fills about 20 percent, the distributor "had substantial information which raised a strong suspicion as to the legitimacy of [the pharmacy's] dispensing practices"); GX 3, at 3.

[74] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,194 ("The combination of a benzodiazepine, a narcotic and carisoprodol is 'well known in the pharmacy profession' as being used 'by patients abusing prescription drugs.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,163 (2010))).

substances than non-controlled substances;[75] fills prescriptions for a high volume of patients who pay for prescriptions in cash;[76] fills a disproportionate volume of controlled substance prescriptions written by only a few prescribers;[77] and orders excessive quantities of a limited variety of controlled substances.[78] *See supra* section III.C. A distributor fails to maintain effective controls against diversion when the distributor continues to distribute controlled substances to a pharmacy that exhibits red flags of diversion without resolving those red flags. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,457 (faulting the distributor for supplying controlled substances "while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances"); *cf. Top RX Pharmacy*, 78 Fed. Reg. 26,069, 26,082 (2013) (applying a similar principle to pharmacies filling prescriptions that contain red flags of abuse or diversion); *see also Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689, 52,699 (2008) (applying a similar principle to list I chemical distributors under 21 U.S.C. § 823(h) ("Fundamental to its obligation to maintain effective controls against diversion, a distributor must review every order and identify suspicious transactions. Further, it must do so prior to shipping the products. Indeed, a distributor has an affirmative duty to forgo a transaction if, upon investigation, it is unable to determine that the proposed transaction is for legitimate purposes.")).[79] A distributor

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[75] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,456; GX 3, at 3.

[76] *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,194 ("'[A]ny reasonable pharmacist knows that a patient that (sic) wants to pay cash for a large quantity of controlled substances is immediately suspect.'" (quoting *E. Main St. Pharmacy*, 75 Fed. Reg. 66,149, 66,158 (2010))).

[77] GX 3, at 3.

[78] *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,421; GX 3, at 3.

[79] Respondent introduced testimony regarding whether Respondent could continue to ship during a due diligence investigation into customer-level red flags of diversion—arguing that there is a certain amount of discretion involved and that stopping shipments would disrupt the supply chain. *See, e.g.*, Tr. 1049, 1050, 1042; 649. The record does not support a finding that Respondent did, in fact, adequately dispel all of the red flags on these customers at any time (before or after distributing), or that Respondent adequately documented purported resolutions of the red flags. The *Masters* decision cannot be read to intend to create a loophole in which a distributor could avoid reporting requirements and continue to ship orders of controlled substances while conducting lengthy investigations into red flags. Such an interpretation would not meet the requirement that a distributor maintain effective controls against diversion. To the extent that, as Respondent argues, there may be some discretion in the

has an obligation to guard against diversion, and as such, must resolve red flags of diversion presented by its customers or decline to ship the controlled substance. 21 U.S.C. §§ 823(b), (e); 21 C.F.R. § 1301.71(a).

When a customer demonstrates red flags of diversion, the distributor must report a suspicious order to DEA unless the distributor conducts a due diligence investigation, which "must dispel all red flags indicative that a customer is engaged in diversion." *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,478. "Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the [DEA] must be informed." *Id.*; *see also id.* at 55,479 n.164 (same).

In upholding DEA's interpretation of the due diligence requirement in the *Masters* decision, the D.C. Circuit Court of Appeals stated:

> As we have emphasized throughout this opinion, it is not necessary for a distributor of controlled substances to investigate suspicious orders if it reports them to DEA and declines to fill them. But if a distributor chooses to shoulder the burden of dispelling suspicion in the hopes of shipping any it finds to be non-suspicious, and the distributor uses something like the SOMS Protocol to guide its efforts, then the distributor must actually undertake the investigation. For example, when an employee uses the SOMS Protocol to confirm or dispel suspicion based on the amount of controlled medication the pharmacy is selling, the employee must request a 'UR,' *i.e.*, a document showing the pharmacy's 'actual dispensing[s] . . . of each drug.' [*Masters Pharm., Inc.*,] 80 Fed. Reg. [55,418,] 55,420 [(2015)]. Moreover, the investigating employee must 'document' customers' explanations for suspicious orders, so that he or she can verify those explanations and make sure they are consistent over time. *Id.* at 55,428 n.21. Additionally, if a customer's explanation for its order is 'inconsistent with other information the investigator has obtained about or from

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decision of when to ship, it is abundantly clear that a distributor cannot ship if it cannot determine that the "proposed transaction is for legitimate purposes," *Novelty Distributors* 73 Fed. Reg. at 52,699, or without resolving "'information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices.'" *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,477 (alteration in original) (quoting *Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,498). Further, Respondent's supply chain argument is weakened by the fact that Respondent had a duty to and was purportedly running reports on prospective customers; therefore, it knew about many of the red flags in the eight exemplar pharmacies before engaging in business with them. *See, e.g.*, GX 25, at 4 (Initial Risk Evaluation Report for Hephzibah Pharmacy LLC); RX 11, at 15 (powerpoint demonstrating turned down prospective accounts based on Pro Compliance Reports).

> the customer, . . . the [investigator] must conduct 'additional investigation to determine whether [its customer is] filling legitimate prescriptions.' *Id.* at 55,477. Finally, the investigation must dispel all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances. *Id.* at 55,478. The Administrator recognized that, if investigating employees fail to take such basic steps, the SOMS (or similar protocol) does not function as an effective tool for dispelling suspicion.

Masters Pharm., Inc., 861 F.3d at 222-23. The D.C. Circuit made clear that all red flags must be resolved or the order must be reported to DEA as suspicious.

In this case, Respondent received numerous Pro Compliance Reports that raised multiple red flags for each of the relevant customers during the relevant time period. *See* GX 20-56; *supra* section III.D. The Pro Compliance Reports themselves clearly identify specific red flags in Respondent's customers' data and frequently recommend further discussions and onsite visits to resolve them. *See, e.g.*, GX 21, at 6; *supra* III.E. Although Respondent produced some minimal evidence consisting of phone logs for some of the exemplar pharmacies in the OSC, *see supra* n.12 and section III.D., which indicated a few instances over the several year timeframe where Respondent had engaged with these customers regarding red flags and/or suspicious orders, there is not adequate documentation as to how Respondent resolved the red flags, even as Respondent continued to fill these orders without reporting them to DEA. Moreover, the GS credibly testified that documentation was an essential component of due diligence. Tr. 298-99 ("[I]f you don't document it how are you going to remember it, how are you going to be able to prove it happened"). The *Masters* decision further pointed out that documentation is essential in maintaining effective controls against diversion to ensure that customers are consistent in their explanations regarding red flags. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,428 n.21. The D.C. Circuit also affirmed the Agency's position that if a distributor undertakes an investigation into its customer's potential diversion, then it must document and "dispel all of the 'red flags' that

gave rise to the suspicion that the customer was diverting controlled substances" to avoid the requirement to report the suspicious order to DEA. *Masters Pharm., Inc.*, 861 F.3d at 222-23.

Here, Respondent acknowledged the paucity of documentation in its records that might show that it had resolved red flags. *See, e.g.*, Tr. 720; GX 9, at 1-2. Contrary to Respondent's argument (ALJ-89, at 101-03, paras. 272-75), the absence of documentation of resolving red flags does indeed constitute evidence that the red flags were never resolved. *See Masters Pharm., Inc.*, 861 F.3d at 218.[80] While Respondent did conduct some due diligence, such as by obtaining Pro Compliance Reports and by preparing its own monthly Market Basket Reports of its customers, ordering the reports without taking appropriate action based on the content of those reports does not come close to satisfying the regulatory obligation to conduct due diligence. These Pro Compliance Reports identify multiple red flags from Respondent's pharmacy customers—demonstrating that Respondent was aware of these red flags—while the records it produced do not resolve them in any substantive way to demonstrate effective controls against diversion. *See, e.g.*, GX 20-56 (the Pro Compliance Reports for the exemplar pharmacies). Respondent's employees even noted occasions where information in the Pro Compliance Reports was specifically concerning to them or where they were aware of additional

[80] To permit Respondent to escape any liability for its lack of adequate controls to protect against diversion merely because Respondent created a policy that did not require documentation of how those controls were exercised would nullify the purpose of the statutory and regulatory requirements. Further, the Agency agrees with the ALJ that Respondent's intentional strategy of not presenting the testimony of any witness who was actually involved in Respondent's purported resolution of red flags further undermines its argument that the red flags were actually resolved. *Id.* Finally, Agency decisions have frequently described the importance of documentation to meet DEA regulatory requirements in other contexts. *See Kaniz F. Khan-Jaffery, M.D.*, 85 Fed. Reg. 45,667, 45,686 (2020) ("DEA's ability to assess whether controlled substances registrations are consistent with the public interest is predicated upon the ability to consider the evidence and rationale of the practitioner at the time that she prescribed a controlled substance—adequate documentation is critical to that assessment." (citing *Cynthia M. Cadet, M.D.*, 76 Fed. Reg. 19,450, 19,464 (2011))). In particular, the *Masters* decision affirmatively stated the requirement for distributors to document their resolutions of red flags and gave a rational basis for that requirement—ensuring that the information is memorialized for the resolution of future indicia of diversion. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,428 n.21. This basis is very apparent here where Respondent's customer base is large and the shipments are numerous. As such, the Agency finds that Respondent's failure to maintain adequate documentation indicates a violation of the requirements to maintain effective controls against diversion.

indicia of diversion or suspicious orders, yet these orders were neither reported to DEA nor is there record evidence to support a finding that Respondent resolved all of the red flags that gave rise to the suspicion. *See, e.g.,* Respondent's employee's comments, at GX 14, at 4 ("[T]his seems quite elevated to me.....????") and 31 ("Henry will give the customer a warning about his Oxy purchases. Too much cash, too much growth. Will re-run and if no improvement will either restrict or cut off completely."). The note documenting this interaction not only fails to offer any resolution of the suspicious circumstances or indicate any reporting to DEA, but also indicates that Respondent knew of the existence of a suspicious order and that the customer was given a warning—providing it with a chance to amend its behavior and further avoid detection from DEA. The regulations require resolution or reporting, not implementation of a "second chance" or "three strikes you're out" program.

A distributor fails to conduct meaningful due diligence that satisfies its regulatory duties where it merely "accept[s] at face value whatever superficial explanation" the pharmacy offers and then fails to independently verify it. *Masters Pharm., Inc.*, 80 Fed. Reg. at 55,457. Further, conducting due diligence but then failing to act on the findings is also inadequate. *See Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,500 (finding the distributor's due diligence efforts to be inadequate where the distributor possessed information that customers were diverting controlled substances yet the distributor continued to provide them with controlled substances). Thus, as the GS credibly testified as an expert witness, the Agency finds that even though Respondent produced some due diligence files to DEA, Respondent seemed to "conduct due diligence and ignore the red flags that are in [its] face and continue to ship" without documenting the resolution of red flags or reporting to DEA, in violation of DEA regulations. Tr. 463; *see also* Tr. 80 (testimony of the Section Chief: "[Y]ou can ask for all these things, but you have to

do something with it."). As the evidence shows, Respondent continued to distribute controlled substances despite the red flags raised in its due diligence files and without either adequately documenting an investigation or resolution of the red flags or refusing to ship and reporting the orders to DEA. As such, Respondent's due diligence was clearly insufficient to meet DEA's legal requirements. *See also* RD, at 120-128 (finding that Respondent did not either dispel all red flags for Folse, Bordelon's, Wallace, Pharmacy Specialties, Dave's Pharmacy, Hephzibah, Wellness, and Wilkinson or report the customers to DEA and refuse to ship).

5. Summary of Public Interest Factors

There is substantial record evidence that Respondent failed to adequately design a suspicious order monitoring system and failed to report suspicious orders to DEA. Further, Respondent failed to report controlled substance orders from customers displaying red flags of diversion and in such cases failed to either cease shipment, or, alternatively, to investigate, resolve, and document the resolution of the red flags. Thus, the Agency finds that Respondent failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels in violation of 21 C.F.R. § 1301.71(a). The Agency also finds that Respondent failed to adequately design and operate a system to disclose to the registrant suspicious orders of controlled substances and report those orders to DEA in violation of 21 C.F.R. § 1301.74(b). *See also* RD, at 138. These violations constitute failures to maintain effective controls against diversion under 21 U.S.C. § 823(b)(1) and demonstrate negative experience in distribution under 21 U.S.C. § 823(b)(4) and weigh strongly in favor of revoking Respondent's Certificates of Registration.

B. Respondent's Integrated Enterprise

DEA has requested revocation of both Respondent's registration at its distribution center in Shreveport, Louisiana, and Respondent's second registration in New Orleans (Jefferson Parish). Respondent argues that DEA has not "alleged any misconduct to have occurred at Respondent's Jefferson location or adduced any evidence or testimony at the hearing regarding Respondent's Jefferson registration." Resp Exceptions, at 49.

The Agency has frequently "treat[ed] two separately organized business entities as one integrated enterprise . . . based on the overlap of ownership, management, and operations of the two entities." *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*, 81 Fed. Reg. 79,188, 79,222 (2016) (citing *MB Wholesale, Inc.*, 72 Fed. Reg. 71,956, 71,958 (2007)). "[W]here misconduct has previously been proved with respect to the owners, officers, or key employees of a pharmacy, the Agency can deny an application or revoke a registration of a second or subsequent pharmacy where the Government shows that such individuals have influence over the management or control of the second pharmacy." *Superior Pharmacy I and Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,341, n.71 (2016). Further, the Agency may revoke a registration without misconduct attributable to that particular registration if the Agency finds that the registrant committed egregious misconduct under a second registration. *Roberto Zayas, M.D.*, 82 Fed. Reg. 21,410, 21,430 (2017) (revoking physician's DEA registration in Florida due to conduct attributed to a Texas registration that had expired).

When a practitioner registrant acts in a manner inconsistent with the public interest, in determining whether to revoke, DEA looks to whether the practitioner can be entrusted with a registration. *See, e.g. Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016). If a practitioner holding multiple registrations cannot be entrusted with one, then it would be difficult to justify entrusting the same practitioner with another in a separate location. Similarly, when a corporate

entity is owned and operated by individuals who have acted inconsistently with the public interest and have misused one of their registrations, the Agency cannot ignore this fact when considering whether to entrust those same individuals with another registration. Furthermore, even if Respondent has not used the Jefferson registration for distribution, this fact does not prevent it from using its registration for distribution in the future.[81] *See Suntree Pharmacy and Suntree Medical Equipment, LLC*, 85 Fed. Reg. 73,753, 73,766 (2020).

The lens through which Congress has instructed the Agency to assess each distributor registration is whether or not such registration is consistent with the public interest. 21 U.S.C. § 823(b). In this case, if Respondent was allowed to simply shift its operations to an entity with the same ownership, then the effect of the violations found herein against Respondent would be a nullity and there would be nothing to prevent Respondent's Jefferson location from continuing to act inconsistently with the public interest. It would be inconsistent with the intent of the CSA to permit such an easily implementable loophole, while it is consistent with Agency decisions to close the loophole by treating the two overlapping entities as one integrated enterprise for purposes of sanction.

Therefore, due to the uncontested commonality of ownership, management, and operations, *see* RD, at 154, the Agency finds that it is appropriate to treat Respondent's two registrations as one integrated enterprise.

V. SANCTION

The Government has established a *prima facie* case to revoke Respondent's registration; therefore, the Agency will review any evidence and argument that Respondent submitted to determine whether or not Respondent has presented "sufficient mitigating evidence to assure the

[81] The ALJ noted that Respondent's exhibits demonstrate that it uses the Jefferson location to "secure controlled substances" and makes distributions out of its Shreveport facility. RD, at 156 (citing RX 1, at 15, 16).

Administrator that [it] can be trusted with the responsibility carried by such a registration." *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23,848, 23,853 (2007) (quoting *Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988)). "'Moreover, because "past performance is the best predictor of future performance," *ALRA Labs, Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.'" *Jayam Krishna-Iyer*, 74 Fed. Reg. 459, 463 (2009) (quoting *Medicine Shoppe*, 73 Fed. Reg. 364, 387 (2008)); *see also Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. at 23,853; *John H. Kennnedy*, M.D., 71 Fed. Reg. 35,705, 35,709 (2006); *Prince George Daniels, D.D.S.*, 60 Fed. Reg. 62,884, 62,887 (1995). The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8248 (2016).

A. Acceptance of Responsibility

1. Standing and Authority to Accept Responsibility

Respondent contends that it has unequivocally accepted responsibility for the proven misconduct and that Irelan, as its Controlled Substance Compliance Officer, was both authorized by Respondent and an appropriate person to accept responsibility on behalf of Respondent. Resp Exceptions, at 8. The Agency agrees that neither Agency regulations nor prior Agency decisions clearly preclude Irelan from accepting responsibility on behalf of Respondent and will therefore

consider his acceptance of responsibility on its merits. Further, the Agency finds that the record supports that Mr. Irelan is responsible for preventing the reoccurrence of Respondent's compliance failures and accepts that Irelan obtained authority from Respondent to accept responsibility at the hearing. *See* Tr. 803 (Irelan is responsible for continued remedial measures), Tr. 1072-74[82]; *but see* Tr. 804 (decisions also go through the chain of command and to the Board).

Ultimately, as explained above, the Agency has long stated that when the Government has presented a *prima facie* case, the burden shifts to the respondent to demonstrate why it can still be entrusted with a registration in spite of its misconduct and the Agency has emphatically emphasized the requirement that respondent unequivocally accept responsibility to establish that trust. *See, e.g., Jeffrey Stein, M.D.*, 84 Fed. Reg. 46,968, 46,972 (2019); *see also Leo R. Miller, M.D.*, 53 Fed. Reg. 21,931, 21,932 (1988) (describing revocation as a remedial measure "based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be trusted with the responsibility carried by such a registration"). For several reasons, Irelan's testimony has not adequately convinced the Agency that Respondent unequivocally accepts responsibility for its past misconduct.

2. Minimization and Characterization of the Misconduct

Here, Irelan accepted responsibility for Respondent failing to effectively apply its customer due diligence in assessing orders of controlled substances, Tr. 722-23, for Respondent

[82] The ALJ did not admit RX 54; however, the Agency accepts that Irelan had authority to make compliance decisions and speak for Respondent in the proceeding.

failing to implement and maintain a suspicious order monitoring system "consistent with best practices for compliance," Tr. 729, 731,[83] and for the fact that "[t]he reporting that was being done, there were three suspicious order reports to the DEA, and that was insufficient," Tr. 731, 733. Irelan also testified that he accepted responsibility for Respondent shipping orders of controlled substances from January 2014 to May 2018 without resolving red flags and testified that he is responsible "for preventing reoccurrence of the company's past failures with respect to application of customer due diligence." Tr. 807, 721.[84]

In discussing his acceptance of responsibility for Respondent's failure to apply its customer due diligence, Irelan specifically testified that, based on his review of Respondent's records before May 2018, Respondent conducted "a tremendous amount of due diligence" on its customers. Tr. 704-05, 710. Irelan caveated that Respondent did not keep the due diligence documentation "in such a way as to make it . . . easily accessible." Tr. 705 (referring to "notes on paper," "notes . . . kept in a database" and "limited notes in our enhanced customer profile"). Nonetheless, the Agency finds that Irelan's statements claiming a "tremendous amount of due diligence" were aimed at minimizing the extent of Respondent's misconduct, which the Agency has previously weighed against a finding of unequivocal acceptance of responsibility. *See Ronald Lynch, M.D.*, 75 Fed. Reg. 78,745, 78,754 (2010) (finding that Respondent did not accept

[83] *Compare* Tr. 731 (Respondent's counsel asked whether the SOM system "was consistent with best practices *and* compliance" (emphasis added)). Whether or not this distinction from the previous statement was an error of speech, the Agency finds this statement to not differ significantly from the previous statement—in both, there was clearly a purposeful avoidance of taking responsibility for the full scope of Respondent's actions and an attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements.

[84] When Government Counsel asked him whether he accepted responsibility in several specific paragraphs of the OSC, Irelan either refused or testified that he was not in a position to answer. *See* RD, at 86. For a few of the paragraphs, Irelan's reservations seemed to be that Respondent conducted at least some additional due diligence on some of the eight pharmacies, but Irelan admitted that the due diligence was not properly applied. *See, e.g.*, Tr. 832-33, 828-29. Given the contested nature of this part of the hearing, the Agency does not find these failures to accept responsibility to imply that Irelan has not accepted responsibility for the misconduct. *See* Resp Exceptions, at 24 (arguing that these were not proven allegations). However, the Agency does find, as explained herein, that Irelan's continual insistence on referring to all of the due diligence that Respondent was conducting—while not documenting it in a retrievable manner nor applying it to the orders—was clearly intended to minimize Respondent's misconduct.

responsibility after noting that he "repeatedly attempted to minimize his [egregious] misconduct"; *see also Michael White, M.D.*, 79 Fed. Reg. 62,957, 62,967 (2014)). Additionally, Irelan's insistence that Respondent was conducting this "tremendous amount" of due diligence "but it was not applied at the order level," *e.g.*, Tr. 828, not only minimizes the violation but fails to acknowledge its scope. At the end of the day, the fact that Respondent was not *applying* the due diligence to the orders (investigating/stopping/reporting) is possibly the most impactful aspect of Respondent's violation. If Respondent was conducting due diligence that was not documented or could not be retrieved such that it could be applied to the actual filling of orders, then Respondent was not exercising effective controls against diversion because employees filling future orders would not know if there were customer-level red flags or whether they were resolved.

Further, Irelan's statements regarding whether Respondent's monitoring systems were "consistent with best practices" also clearly minimized the scope of Respondent's misconduct and did not demonstrate a full grasp of the breadth of the misconduct alleged—which was that Respondent had violated DEA regulations,[85] not failed to implement "best practices." Respondent's attempt to characterize the DEA regulations as being merely best practices as opposed to affirmative legal requirements both minimizes the severity of the violations and also demonstrates a failure to grasp of the significance of the requirements.

3. Scope of the Misconduct

The requisite acceptance of responsibility hinges on the respondent demonstrating an understanding both of the past misconduct and its extent. *See Jones*, 881 F.3d at 833. Here, the

[85] Even if Respondent chose its language to avoid drawing legal conclusions, the use of the term "best practices" was not sufficient to accurately describe the violations found herein and was clearly aimed at minimizing them. *See supra* n.83.

ALJ found that Irelan did not "acknowledge the *scope* of the Respondent's misconduct," and therefore, his acceptance was equivocal. RD, at 151 (citing *Arvinder Singh, M.D.*, 81 Fed. Reg. at 8250-51).

As Respondent stated in its Exceptions:

> Multiple United States Courts of Appeal have upheld DEA's acceptance of responsibility requirement as rational on the grounds that if a respondent "does not understand the extent of the past misconduct or its current responsibilities under the law, the DEA rationally could doubt that the [respondent] would faithfully comply in the future with its obligations under the CSA." *Jones Total Health Care Pharmacy, LLC v.* [*Drug Enf't Admin.*], 881 F.3d 823, 833 (11th Cir. 2018); *accord MacKay v.* [*Drug Enf't Admin.*], 664 F.3d 808, 820 (10th Cir. 2011) (admittance of fault is relevant to Administrator's consideration of whether a respondent will change its future behavior). As Respondent's current Compliance Director, Mr. Irelan has assessed Respondent's past controlled substance compliance failures and is responsible for preventing their reoccurrence.

Resp Exceptions, at 13.

In contrast to Respondent's final statement above, there were a few times where Irelan's limited involvement and knowledge of the misconduct indisputably impeded his ability to accept full responsibility, such as when, regarding Wellness Pharmacy, he was unable to state what due diligence "specifically was performed for that account." Tr. 831. The Agency finds that Irelan's admission that he had not familiarized himself with the specific due diligence performed by Respondent for the exemplar pharmacies demonstrates that he did not actually have the knowledge required to accept unequivocal responsibility on behalf of Respondent for the full extent of the violations found. Irelan's assertion that Respondent did conduct a "tremendous amount" of due diligence is also inconsistent with his stated lack of knowledge regarding the amount of due diligence conducted for the limited number of customers included in the OSC's allegations. It seems logical that in cultivating an understanding of Respondent's violations in order to adequately accept responsibility, Irelan would have focused his review on the customers

most relevant to the allegations. Therefore, Irelan does not seem to have been equipped to meet Respondent's burden in accepting responsibility.

4. Trust in Respondent

Although the Agency does not challenge Irelan's authority to act on behalf of Respondent in accepting responsibility, the burden is on *Respondent* to credibly and candidly demonstrate that it can be entrusted with a registration. Respondent chose to meet that burden by presenting Irelan's testimony in lieu of a principal or an individual who had knowledge of the full scope of the violations. Although the Agency does not contest that Respondent *could* choose Irelan to accept responsibility on its behalf, that finding does not mean that Irelan was equipped to do so unequivocally.

It is noted that the Agency has long held that the misconduct of an entity's principal is properly considered in determining whether to revoke the entity's registration. *Chip RX, L.L.C., d/b/a City Ctr. Pharmacy*, 82 Fed. Reg. 51,433, 51,438 (2017) (citing *G & O Pharmacy of Paducah*, 68 Fed. Reg. 43,752, 43,753 (2003)). An essential element of Respondent's showing of trust is that the registrant and its principals accept responsibility for their misconduct by acknowledging their wrongdoing. *Sun & Lake Pharmacy,* 76 Fed. Reg. 24,533 (citing *Medicine Shoppe*, 73 Fed. Reg. at 387; *Jackson*, 72 Fed. Reg. at 23,853; *Kennedy*, 71 Fed. Reg. at 35,709). In this case, at least one of Respondent's principals, Paul Dickson, Sr., bears at least some responsibility for the misconduct, and Irelan bears none. *See* Tr. 723.

Irelan opined that C.G. and Jacob Dickson, who were in charge of compliance during the relevant time period, were responsible for Respondent's misconduct, but was not sure enough of the "dynamics" or "reporting process" to opine about whether Paul Dickson, Sr., carried any responsibility. Tr. 808-09. The extent of the misconduct is an important factor in the Agency's

ability to determine whether to entrust Respondent with a registration and Irelan's inability to testify to the level of involvement and knowledge of Respondent's principals in the misconduct demonstrates another reason why the Agency cannot deem his acceptance of responsibility to be adequate such that the Agency can entrust Respondent with a registration. In fact, Respondent's submitted evidence includes testimony from the Hearing on the Motion for Temporary Restraining Order[86] in which Paul Dickson, Respondent's president, testified that he was primarily responsible for development of Respondent's SOM program and that he designed the system. RX 1, at 33. Paul Dickson further told the Court that in designing the system, he knew that he "didn't do a perfect job," but that "it was the best that [he] could do. And [he] think[s] it's dang good. And [he doesn't] think a single person has gotten hurt by [their] drugs. [He] sure do[esn't] know of one . . . . So [he] think[s] it works." RX 1, at 57. These statements from the president of a family-owned and -operated company so strongly miss the point of the requirements of a DEA registrant that they further undercut the Agency's ability to entrust Respondent with a registration. To equate a registrant's compliance with an agency's closed regulatory system with the consequence of knowing whether anyone was hurt "by [their] drugs" exhibits a stark misunderstanding of the regulatory requirement.

The Agency finds that Irelan's inability to describe Paul Dickson's involvement in the proven misconduct further demonstrates the inadequacy of Respondent's acceptance of responsibility in this proceeding. In all, Irelan's lack of understanding and recognition of the full

[86] It is noted that the ALJ excluded pages 147 to 216 of this transcript as irrelevant, but allowed pages 1 through 146 because Respondent offered it as remedial, mitigation, or community impact evidence. ALJX 59, at 6 (citing ALJX 29, at 2, 4.) Although it is also noted that the hearing in which these statements were made was related to the public interest in the context of the ISO, the ALJ found, and the Agency agrees, that this evidence bears some relevance to the current inquiry. *Id.* Furthermore, Respondent argues in its Exceptions that "[t]his testimony is relevant evidence of Respondent's credibility and good faith intent in working with DEA to stop diversion." Resp Exceptions, at 31. For the reasons stated above, the Agency finds that, if anything, Paul Dickson's remarks seem indignant that DEA is pursuing enforcement, seem aimed at minimizing the misconduct, and display a lack of understanding and respect for the regulatory requirements.

scope of the misconduct and attempts to minimize the misconduct lead the Agency to conclude that Respondent's acceptance of responsibility was equivocal and insufficient to ensure that Respondent can be entrusted with a registration.

B. Remedial Measures

When a registrant fails to make the threshold showing of acceptance of responsibility, the Agency has stated that it need not address the registrant's remedial measures. *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,810 (2015); *see also Ajay S. Ahuja, M.D.*, 84 Fed. Reg. at 5498 n.33; *Jones Total Health Care Pharmacy, L.L.C., & SND Health Care, L.L.C.*, 81 Fed. Reg. at 79,202; *The Medicine Shoppe*, 79 Fed. Reg. 59,504, 59,510 (2014). A registrant does not unequivocally accept responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195*, 77 Fed. Reg. 62,316, 62,346 (2012). Refusal to acknowledge the *full scope of misconduct*, even with remedial measures, is a risk to the public interest. *Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8250-51 (2016) (emphasis added).

The ALJ characterized Respondent's remedial measures as "impressive." RD, at 152. The Agency similarly credits the efforts that the record reflects Respondent undertook to improve its compliance with DEA's requirements after being served with the OSC. As the ALJ appropriately stated, the Agency has also made it abundantly clear that remediation alone is not adequate to avoid a sanction and that limited-to-no-weight is given to remedial measures when the effort is not made until after enforcement begins. *See Mireille Lalanne, M.D.*, 78 Fed. Reg. 47,750, 47,777 (2013) (quoting *Liddy's Pharmacy, L.L.C.*, 76 Fed. Reg. 48,887, 48,897 (2011) ("The Agency has recognized that a cessation of illegal behavior only when 'DEA comes knocking at one's door,' can be afforded a diminished weight borne of its own opportunistic timing.")); *see also Southwood Pharm. Inc.*, 72 Fed. Reg. at 36,503 (giving no weight to

respondent's "stroke-of-midnight decision" to cease supplying suspect pharmacies with controlled substances and to employ a compliance officer).[87]

Additionally, the ALJ found that, based on prior Agency decisions, he could give no weight to Respondent's remedial measures given the lack of Respondent's unequivocal acceptance of responsibility. RD, at 152.[88, 89] As the Agency has consistently held, "past performance is the best predictor of future performance." *Lesly Pompy, M.D.*, 84 Fed. Reg.

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[87] In its Exceptions, Respondent points to the factual distinctions between cited cases in the RD and the circumstances in this case and also points to numerous other settled cases that, in Respondent's opinion, demonstrate that the sanction here is unfair. Resp Exceptions, at 25 and 33. However, "the issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent," and it is the respondent's burden to bear. *See, e.g., Stein,* 84 Fed. Reg. at 46,972. And contrary to Respondent's arguments, the proposed sanction is supported by similar sanctions in other recent distributor adjudications where the Agency similarly found that respondents' registrations were inconsistent with the public interest and that those respondents had not demonstrated that they could be entrusted with a registration. *See Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,487 (rejecting the ALJ's sanction because it was "insufficient to protect the public interest. While [the Agency is] mindful of the corrective measures engaged in by Respondent, its sales of extraordinary quantities of controlled substances to entities which it had reason to know were diverting the drugs caused extraordinary harm to public health and safety."); *see also Masters Pharm., Inc.*, 80 Fed. Reg. at 55,501.

[88] Respondent repeatedly asserts that these adjudications are difficult to defend due to what it claims is an unfair system—that Respondent must accept responsibility prior to knowing what misconduct has been proven. Resp Exceptions, at 7. Respondent chose litigation strategies presumably based on the longstanding structure and content of Agency decisions in these adjudications and the Agency does not fault it for those decisions. In the end, Respondent had the burden to prove that it could be entrusted with a registration and it has failed to meet that burden. *See Masters Pharm., Inc.*, 861 F.3d 206 (D.C. Cir. 2017) (rejecting arguments that DEA's structure of requiring acceptance of responsibility is unfair, because "under longstanding DEA precedent, once DEA presents enough evidence at hearing to show that a registered vendor or distributor of controlled substances has 'committed acts inconsistent with the public interest,' the 'registrant must present[] . . . mitigating evidence' including evidence that it has 'accept[ed] responsibility for its actions and demonstrate[d] that it will not engage in future misconduct'" (quoting *Medicine Shoppe-Jonesborough*, 73 Fed. Reg. 364, 387 (2008)). Furthermore, the Agency's finding on this issue does not hinge on whether Irelan has accepted responsibility for each proven allegation, but instead hinges on Irelan's persistent minimization of the misconduct and further on Respondent's overall failure to demonstrate that *Respondent* has *unequivocally* accepted responsibility and can be trusted with a registration.

[89] Respondent argues that Milione's testimony regarding the August 2016 meeting with Paul Dickson, Sr., *supra* n.8, demonstrates Respondent's "good faith and sincerity, which flatly contradict the ALJ's intent-laden description of Respondent's compliance as 'cavalier'" and argues that this fact is relevant in considering Respondent's likelihood towards recidivism. Resp Exceptions, at 30 (citing RD, at 156). The Agency cannot give this meeting or Paul Dickson's sincerity during this moment in time the weight that Respondent requests it be afforded given that the evidence demonstrates that for approximately two years prior to this meeting and two years afterwards, Respondent was not complying with DEA regulations. Further, Respondent did not present the Agency with Paul Dickson's testimony at this hearing to be able to weigh his credibility and sincerity either in 2016, when this meeting occurred, or at the time of the hearing. The transcribed testimony that Respondent did submit from Paul Dickson demonstrated that he believed his SOM system to be "dang good"—a statement with which the Agency emphatically disagrees. *See* RX 1, at 57.

57,749, 57,761 (2019); *see also Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 833 (11th Cir. 2018) (affirming refusal to consider remedial measures where registrant did not accept responsibility for its misconduct); *Pharmacy Doctors Enterprises, Inc. v. Drug Enf't Admin.*, 789 F. App'x 724, 2019 WL 4565481, at *7–8 (11th Cir. Sept. 20, 2019) (same).[90]

In this case, even if the Agency gave weight to Respondent's remedial measures, the measures are outweighed by the fact that it has not adequately established that Respondent as an entity fully understands the scope of the misconduct such that it can be entrusted with regulatory compliance in the future.

C. The Extent of the Misconduct

The record demonstrates that Respondent's violations of the law were not isolated occurrences, but took place over the course of four years and involved multiple customers. *See Garrett Howard Smith, M.D.*, 83 Fed. Reg. at 18,910 (collecting cases) ("The egregiousness and extent of [the] misconduct are significant factors in determining the appropriate sanction."). In spite of its self-described status as a privately-owned company that has been in business for 177 years,[91] Respondent maintained sparse documentation of its SOM procedures generally and maintained very little documentation of its resolution of red flags of diversion displayed by its customers or of individual suspicious orders. The record evidence demonstrates that Respondent attended two conferences, held a personal meeting with DEA, and received multiple letters in

[90] *See also Hills Pharmacy, LLC*, 81 Fed. Reg. 49,815, 49,847 (2016) ("[T]here is no need to consider Respondent's remedial efforts as they are rendered irrelevant by its failure to acknowledge its misconduct."); *Daniel A. Glick, D.D.S.*, 80 Fed. Reg. 74,800, 74,810 (2015) ("[S]ince the Respondent has not tendered an unequivocal acceptance of responsibility, under established Agency precedent, [it] is foreclosed from a favorable result in these proceedings and the issue of remedial actions is irrelevant.").

[91] *See also* RX 1, at 21 (estimating Respondent's number of retail pharmacy customers at "approximately 600 primary . . . and another 200 secondary that fluctuates") and 22-23 ("[O]nly competition are what's called 'the big three,' the global companies").

which DEA emphasized the critical importance of a distributor's role in preventing diversion given the opioid crisis in the nation and reminded distributors of their obligations under the law. A letter from DEA dated September 27, 2006, stated "[G]iven the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm." GX 3, at 2. In spite of Respondent's established knowledge regarding the criticality of its role in preventing "dangerous and potentially lethal consequences," Respondent did not adequately resolve or document investigation into the numerous red flags indicating diversion that its own Pro Compliance Reports identified on the exemplar pharmacies and failed to report a multitude of suspicious orders to DEA.

D. Deterrence

Finally, both specific and general deterrence strongly weigh in favor of revoking Respondent's registration. *See Daniel A. Glick, D.D.S.*, 80 Fed. Reg. at 74,810. The record demonstrates that Respondent violated DEA regulations over a lengthy time period—failing to report a multitude of suspicious orders to DEA and depriving DEA of valuable information about pharmacies and practitioners who might have been engaging in diversion or violating their obligations as DEA registrants, thus contributing to the country's devastating prescription drug abuse problem. Under these circumstances and on this record, a sanction less than revocation[92]

[92] Respondent argues without support that a sanction short of revocation would serve the same deterrence goals and would prevent harm to the community that would result from closing Respondent. Resp Exceptions, at 28, 31. The Agency does not consider community impact in its decisions. *See infra* n.96. As Respondent notes, it is difficult to know what level of sanction would deter future non-compliance in the registrant community, but in Respondent's case, where the violations were blatant, long-term, and impactful, the Agency finds, given the record before it, that revocation offers an appropriate deterrent effect. Furthermore, again, Respondent has not adequately established trust, *see supra* Section V.A.4, which is crucial to demonstrate the appropriateness of a sanction less than revocation under the Agency's consideration of specific deterrence. Respondent also argues that the ALJ erred in its deterrence analysis by failing to consider the Government's purported unwillingness to engage Respondent in settlement negotiations. Resp Exceptions, at 33-35. While a settlement agreement between the Government and a respondent

would send a message to the current and prospective registrant community that compliance with DEA regulations is not a condition precedent to maintaining a DEA registration and that a distributor can spend years insufficiently reporting suspicious orders and inadequately resolving red flags presented by its customers, so long as it finally invests in the procedures it should have had in place all along after it is caught and faces potential consequences.[93]

Although Respondent has implemented remedial measures, it has not adequately demonstrated that its leadership can be entrusted to continue these measures and prevent reoccurrence of what happened prior to the issuance of the OSC, which amounted to a SOM system that was not designed or operated in a way that would adequately prevent diversion of controlled substances nor provide DEA with information critical to its mission. Respondent argues that the ALJ erred in finding that "the continued registration of a fully remediated registrant with an 'impressive' anti-diversion regime, along with evidence of good faith desire to prevent diversion, does not serve the public interest."[94] Resp Exceptions, at 1. However, Respondent's argument neglects to mention that remediation is irrelevant without continued trust. Respondent wants credit for "commission[ing] former top DEA officials to design their

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may be a way to provide enforceable assurances of the respondent's future compliance, the parties have not reached such a settlement here. Accordingly, and although the Agency has considered alternative sanctions as Respondent has requested, it has decided that revocation currently is the most appropriate sanction as explained herein.

[93] DEA decisions have demonstrated concern that giving weight to last minute remedial measures would show the regulated community that a registrant "can unlawfully distribute controlled substances until [it] gets caught, and as long as [it] then acknowledges wrongdoing and puts on evidence that [it] has reformed, [it] will get a slap on the wrist." *David Ruben, M.D.*, 78 Fed. Reg. 38,363, 38,387 (2013); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,504 (2007) ("A precedent which ignores how irresponsibly a registrant has acted and allows it to maintain its registration based on its claim of having reformed its business practices, could well prompt other registrants to ignore their obligations under the Act and sell massive quantities of controlled substances to diverters.").

[94] Respondent argues that its "current conduct is the best evidence that its continued registration is consistent with the public interest." Resp Exceptions, at 7. However, remediation is notably not an enumerated public interest factor under 21 U.S.C. § 823(b). Remediation is a factor that the Administrator considers in reviewing the extent to which sanctions are appropriate and only after the Government has made a *prima facie* case demonstrating that the allegations support a finding that Respondent's continued registration is not in the public interest. *See, e.g., Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. at 23,853.

ideal anti-diversion system," *id.*, because it believes that as long as it has invested the money now, it will prevent DEA from enforcing against it. There are several considerations other than remediation that the Agency uses in determining sanction as explained herein. The fact is that, under these circumstances and on this record, Respondent has not adequately convinced the Agency that it can be entrusted with a registration—its acceptance of responsibility did not prove that it or its principals understand the full extent of their wrongdoing, the effect that it had on the Agency and the American public, and the potential harm that it caused.[95] It was Respondent's burden to prove that it could be entrusted to protect the public interest in maintaining a DEA registration—and it has failed to do so.

Having reviewed the record in its entirety, the Agency finds that Respondent cannot be entrusted with a DEA registration and orders that its registration be revoked. The Agency addresses collateral matters and additional issues raised in Respondent's Exceptions before issuing a final Order.

VI. Motion to Reopen

On January 5, 2022, Respondent filed a Motion to Reopen the Administrative Record. Respondent seeks to introduce evidence of post-hearing conduct that it argues demonstrates

[95] Respondent attached to its Exceptions the Department of Justice Office of the Inspector General (OIG) September 2019 Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts to Control the Diversion of Opioids—claiming that the report is DEA's motivation for pursuing "the harshest sanction" against Respondent. The report is dated September 2019—a month after the ALJ's issuance of the RD. Furthermore, DEA subpoenaed Respondent as early as February 1, 2018; therefore, temporally, the OIG's findings could not have motivated the Agency's investigation into Respondent. Such allegations are a distraction from the issue at hand—Respondent failed to comply with its regulatory obligations and neither the Agency nor the country could possibly have the ability to know what might have happened had those suspicious orders been reported to DEA and to what extent diversion and abuse might have been prevented. What the Agency does know is that Respondent's failures were monumental, and Respondent clearly misses the point in arguing that "had the Respondent more consistently reported suspicious orders with the DEA, it has been established that the reports would have been ignored." Resp Exceptions, at 5.

acceptance of responsibility and successful remediation.[96] Although not specifically contemplated in the CSA or regulations, DEA decisions have repeatedly held that the Administrator may, in her discretion, order that the administrative record be reopened. The party moving to reopen, however, bears a heavy burden. *See INS v. Abudu*, 485 U.S. 94, 110 (1988); s*ee also Cities of Campbell v. FERC*, 770 F.2d 1180, 1191 (D.C. Cir. 1985) ("Reopening an evidentiary hearing is a matter of agency discretion and is reserved for extraordinary circumstances." (citations omitted)); *Nance v. EPA*, 645 F.2d 701, 717 (9th Cir. 1981).

The Agency finds that Respondent has not met its burden to reopen the record. In all DEA administrative proceedings, there is inevitably at least some delay between the hearing and the final decision of the Administrator.[97] Allowing parties to reopen the record to introduce evidence of acceptance of responsibility and remedial measures taken during that delay would create a recursive loop further delaying the conclusion of proceedings to the detriment of the public interest. *See, e.g., Abudu*, 485 U.S. at 107; *Qoku v. Gonzales*, 156 F. App'x. 703, 705 (5th Cir. 2005). As the Supreme Court observed in *Vermont Yankee Nuclear Power Corp. v. NRDC*, "[a]dministrative consideration of evidence . . . always creates a gap between the time the record

[96] Respondent also requests to reopen the record to introduce evidence of the impact revoking its registration would have on the community. Motion to Reopen, at 20-22. The Agency has consistently found that community impact is not a relevant consideration under the public interest factors. *E.g.*, *Stephen E. Owusu*, D.P.M., 87 Fed. Reg. 3343, 3351 n.21 (2022); *George Pursley, M.D.*, 85 Fed. Reg. 80,162, 80,188 n. 82 (2020); *Frank Joseph Stirlacci, M.D.*, 85 Fed. Reg. 45,229, 45,239 (2020). Accordingly, Respondent's community impact evidence is not grounds to reopen the record. Further, Respondent made arguments that it should be allowed to introduce evidence that it concedes is not an independent basis to reopen the record but argues is properly admitted if the record is reopened. Reply ISO Motion to Reopen, at 12. Nonetheless, the Agency is not reaching a finding on the admissibility of this evidence because it is not granting Respondent's Motion to Reopen.

[97] The delay between the hearing and the issuance of the final decision in this matter was longer than is typical for the Agency, but the proceedings were delayed partially at Respondent's request. On March 9, 2020, Respondent wrote a letter to the then-Acting Administrator asking that the Agency postpone issuing a Final Order "to allow the COVID-19 crisis to abate or the parties to reach a final settlement . . . ." *See* Letter from Respondent. Respondent then requested yet another delay in its Motion to Reopen asking that the Administrator delay the issuance of a final order "until after [Respondent's] new counsel has had an opportunity to resolve the matter with DEA's Chief Counsel." Motion to Reopen, at 4, n.4. Respondent cannot request to delay the proceedings and then claim that a failure to reopen the record is somehow prejudicial to Respondent because of its requested delay.

is closed and the time the administrative decision is promulgated . . . . If upon the coming down of the order litigants might demand rehearings as a matter of law because some new circumstance has arisen, some new trend has been observed, or some new fact discovered, there would be little hope that the administrative process could ever be consummated in an order that would not be subject to reopening." 435 U.S. 519, 554-55 (1978) (quoting *ICC v. Jersey City,* 322 U.S. 503, 514 (1944) (citing *Northern Lines Merger Cases,* 396 U.S. 491, 521 (1970)).

Respondent had the opportunity to, and did, introduce evidence related to its acceptance of responsibility and remedial measures at the hearing. That evidence was entered into the record and considered in the ALJ's Recommended Decision and this Final Order.

VII. *Lucia*

The Agency has carefully considered Respondent's Exceptions to the Recommended Decision, has addressed them throughout the record, and addresses the remaining herein.

In its Exceptions, Respondent notes that "as [it] has repeatedly and consistently objected, including at the hearing, this entire proceeding was unconstitutional." (citing Tr. 20:23-22:17). Respondent contends that "[t]he presiding ALJ in this matter was unconstitutionally appointed when these proceedings began and unconstitutionally continued to preside over these proceedings after the Attorney General purportedly ratified his appointment." (citing *Lucia v. Securities and Exchange Comm'n*, 138 S. Ct. 2044, 2055 (2018) (hereinafter, *Lucia*)). The Agency will note the factual sequence of events surrounding Respondent's *Lucia* claims.

Respondent's Prehearing Statement, filed on August 3, 2018, averred, "Respondent may file a motion before this Tribunal related to the constitutionality of the DEA's administrative process given the U.S. Supreme Court's recent decision in [*Lucia*]." ALJX 8, at 37. During the Prehearing Conference, Respondent's attorney stated, "with regards to the *Lucia* case, this is

obviously no disrespect intended to the Court but we do think that it's a significant issue that should we proceed to hearing, we do want to address and I would like to file a motion about it." The ALJ replied, "Well, if you're going to file a motion about it, I obviously would need to take a look at it . . . . Apparently, if you file a motion, there's a good chance you'll wind up with a different Judge . . . . I'm just putting you on notice that that's what's likely to happen." Prehearing, Tr. 36. The ALJ ordered that "[y]ou obviously can file motions tomorrow if you want to but any motions I'm going to need to rule on I would like to have no later than October 23rd. . . ." Tr. 42-43.

On October 26, 2018, Respondent submitted a letter on the record alerting the Tribunal that it had commenced an action in the United States District Court for the Western District of Louisiana seeking an "injunction enjoining DEA and DOJ from requiring Morris & Dickson to appear in any administrative proceeding, including the upcoming hearing scheduled for November 13, 2018, unless and until a constitutionally valid administrative system has been established." ALJX 26, at 1. On October 31, 2018, Respondent filed another letter with the Tribunal explaining that it did not file a motion with the ALJ because the Agency "has no authority to entertain a facial constitutional challenge" and that "[t]he Louisiana Court will resolve that question. Morris & Dickson simply provides this Tribunal notice of that filing and requests sufficient time to allow the Louisiana Court (and, if necessary, the Fifth Circuit Court of Appeals) to make its ruling." ALJX 34, at 1-2.

On December 31, 2018, Respondent submitted a letter notifying the Tribunal that "[o]n December 28, 2018, the District Court in the Western District of Louisiana dismissed Respondent's complaint without prejudice, finding that it did not have jurisdiction to hear Morris & Dickson's claims" and attaching the decision. ALJX 47, at 1. The Decision stated that,

although Respondent's argument was "somewhat close," "in light of the policy problem created by crafting a 'constitutional claim' exception to Congress's ability to channel initial review through agencies, the Court finds that Morris & Dickson's separation-of-powers claims are not 'wholly collateral' to the proceeding before Judge Dorman because they were raised in an attempt to delay or defeat administrative enforcement of the CSA." *Id.* at 30.

On January 15, 2019, the ALJ issued an Order Lifting the Stay and Third Prehearing Ruling. ALJX 51. The Order stated that Respondent indicated during a telephonic conference on the previous day that it "w[ould] not seek to maintain the stay in this case pending its appeal to the United States Court of Appeals for the Fifth Circuit"[98] and that "it w[ould] not file a motion seeking to recuse [the ALJ] from this case based on the Supreme Court's decision in *Lucia* . . . ." *Id.* at 1.

The next time Respondent raised the *Lucia* issue was at the beginning of the hearing on May 13, 2019. Respondent's lawyer made a self-described "statement of the record, simply," Tr. 23, that "we respectfully renew for the record our objection to the hearing and proceeding." Tr. 22. However, Respondent's lawyer also agreed that Respondent was ready to go to hearing that day and made no further motions or requests for a new ALJ. Tr. 24.

On October 25, 2018, the Attorney General ratified the prior appointment of the DEA ALJs, including ALJ Dorman, and "approved their appointments as his own under the Constitution." *See* Office of the Attorney General, Order No. 4.315-2018.[99] It is noted that, at the time that the hearing took place in this matter, ALJ Dorman's appointment as an Administrative Law Judge had been ratified. Respondent never formally requested reassignment

[98] Respondent's appeal to the United States Court of Appeals for the Fifth Circuit was dismissed by its own motion. *See Morris and Dickson v. William Barr, et. al.*, No. 19-30043, 2019 WL 3230978 (5th Cir. Apr. 1, 2019).
[99] Although not considered material to this Decision, a copy of this Order will be included in the administrative record for future reference.

nor availed itself of the opportunity to request interlocutory review to the Administrator on any ruling of the ALJ or any *Lucia*-related issue pursuant to 21 C.F.R. § 1316.62. Had Respondent contested the matter formally with the Agency, the Agency would have assigned another ALJ, *see* Prehearing, Tr. 36, and saved significant Agency resources. The Agency further finds that ALJ Dorman's appointment was ratified before the hearing. Due to Respondent's calculated choice to preserve the matter for the record, Tr. 23, but not raise it in any way that the Agency might have had the capacity to address and remedy itself, the Agency considers the argument waived for purposes of finalizing this adjudication.

Having found that Respondent cannot be entrusted with a DEA registration, the Agency issues the following Order revoking Respondent's DEA registrations.

ORDER

Pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a)(4) and 21 U.S.C. § 823(b), (e), I hereby revoke DEA Certificates of Registration Nos. RM0314790 and RM0335732 issued to Morris & Dickson, Co., LLC. Further, pursuant to 28 C.F.R. § 0.100(b) and the authority vested in me by 21 U.S.C. § 824(a)(4) and 21 U.S.C. § 823(b), (e), I hereby deny any pending application of Morris & Dickson, Co., LLC to renew or modify these registrations, as well as any other pending application of Morris & Dickson, Co., LLC. This Order is effective **[insert Date Thirty Days From the Date of Publication in the Federal Register]**.

Date: MAY 19 2023

Anne Milgram
Administrator

BILLING CODE: 4410-09-P

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

Docket No. 18-31
MORRIS & DICKSON CO., LLC
ORDER

On May 19, 2023, I issued and served on the parties a Decision and Order (the Decision and Order) revoking, effective 30 days from the date of publication in the Federal Register, Certificate of Registration Nos. RM0314790 and RM0335732 issued to Morris & Dickson, Co., LLC (Respondent). By motion dated May 20, 2023, Respondent requested a stay of the Decision and Order. On May 21, I issued an order soliciting additional information from Respondent and asking the Government to respond to Respondent's Motion for Stay. On May 22, both parties responded. Respondent clarified that it was requesting a stay of at least 90-to-120 days so that it can renew settlement negotiations with the Government. Respondent's May 22, 2023 Letter re Motion for Stay, at 1. Respondent also stated that a stay was necessary to mitigate the impact on its "customers, employees, and other stakeholders," including pharmacies, hospitals, and patients. *Id.* at 4-5. The Government indicated that it opposed any stay request, but stated that it was "open to settlement offers" and suggested it was willing to engage in settlement negotiations with Respondent. Government's Opposition to Motion to Stay, at 3.

Upon consideration of the entire record before me, the public interest—in particular, the potential need for Respondent's customers and their patients to find new suppliers given the revocation of Respondent's registrations—and the possibility for renewed settlement negotiations, I hereby order that the May 19, 2023 Decision and Order will be effective on ***[insert Date Ninety Days From the Date of Publication of the May 19, 2023 Decision and Order in the Federal Register]***—ninety days from the date of the Decision and Order's

publication in the Federal Register. This change is reflected in the published Decision and Order.

It is so ordered.

Date: May 23, 2023

Anne Milgram
Administrator

M&D Exh. 1(C) - June 16, 2023 Indefinite Stay Order

United States Court of Appeals for the Fifth Circuit

No. 23-60284

MORRIS & DICKSON COMPANY, L.L.C.,

Petitioner,

versus

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review from an Order of the
Drug Enforcement Agency
Agency No. 88 Fed. Reg. 34523

UNPUBLISHED ORDER

Before HAYNES, ENGELHARDT, and OLDHAM, *Circuit Judges*.

PER CURIAM:

On the showing made, IT IS ORDERED that Petitioner's opposed motion for stay pending appeal is GRANTED.

M&D Exh. 1(D) – November 3, 2023 Abeyance Order

United States Court of Appeals

FIFTH CIRCUIT
OFFICE OF THE CLERK

LYLE W. CAYCE
CLERK

TEL. 504-310-7700
600 S. MAESTRI PLACE,
Suite 115
NEW ORLEANS, LA 70130

November 08, 2023

MEMORANDUM TO COUNSEL OR PARTIES LISTED BELOW:

No. 23-60284 Morris & Dickson v. DEA
Agency No. 88 Fed. Reg. 34523

Enclosed is an order entered in this case.

Sincerely,

LYLE W. CAYCE, Clerk

Shea E. Pertuit

By: _____
Shea E. Pertuit, Deputy Clerk
504-310-7666

Mr. Daniel J. Aguilar
Ms. Anita J. Gay
Mr. Harry Graver
Mr. Jeffrey Johnson
Mr. Stephen Matthew Krsacok
Mr. Joshua Marc Salzman
Ms. Anna Manchester Stapleton

United States Court of Appeals for the Fifth Circuit

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MORRIS & DICKSON COMPANY, L.L.C.,

Petitioner,

versus

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review from an Order of the
Drug Enforcement Agency
Agency No. 88 Fed. Reg. 34523

ORDER:

IT IS ORDERED that the joint motion of the parties to stay further proceedings in this court, to facilitate settlement discussions, is GRANTED in part, in that the matter is stayed for ninety (90) days from the date this order is entered, whereupon the deadlines for filing briefs shall be reinstated with DEA's answering brief due 14 days from such date; and DENIED in all other respects.

The parties shall jointly file a status report forty-five (45) days from the date this order is entered, updating the progress of any discussions referenced in the joint motion.

KURT D. ENGELHARDT
United States Circuit Judge

CIVIL SETTLEMENT AGREEMENT

This Civil Settlement Agreement ("Civil Settlement Agreement") is entered by and between the United States Attorney's Office for the Western District of Louisiana ("USAO"), acting on behalf of the United States Department of Justice and the United States Drug Enforcement Administration ("DEA") (collectively referred to as the "United States") and Morris & Dickson Company, LLC ("Morris & Dickson") (each a "Party" and collectively the "Parties").

RECITALS

A. Morris & Dickson owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II – V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. (Controlled Substances Act or "CSA") (each a "Distribution Center" and collectively the "Distribution Centers").

B. In determining whether to register an applicant to distribute Schedule II – V controlled substances, the Attorney General, acting through the DEA, must consider the applicant's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels. 21 U.S.C. §823(b)(1) and (e)(1).

C. Section 1301.74(b) of Title 21 of the Code of Federal Regulations requires registrants to operate a system to identify suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered.

D. Morris & Dickson acknowledges that its DEA-registered distribution centers were and are required to comply with the CSA and the regulations promulgated thereunder, including the requirement described in Paragraph C.

E. The DEA, by its Administrator, has pending an Order to Show Cause for Morris & Dickson to appear and show cause why the DEA registration of Morris & Dickson should not be revoked. *See In the Matter of Morris & Dickson Co., LLC*, DEA Administrative Court Docket No. 18-31.

F. In parallel to the DEA Administrative Proceeding set forth in Paragraph E, the United States Attorney's Office for the Western District of Louisiana conducted a civil investigation with the assistance of the DEA's New Orleans Field Division into alleged failures by Morris & Dickson to inform the DEA of suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b).

G. The United States contends that Morris & Dickson failed to inform the DEA of suspicious orders as required by 21 C.F.R. §1301.74(b). The United States further contends that these violations subject Morris & Dickson to civil penalties under 21 U.S.C. §§842(a)(5) and (c)(1), as well as injunctive relief under 21 U.S.C. §843(f).

H. This Settlement Agreement is neither an admission of liability by Morris & Dickson nor a concession by the United States that its claims are not well founded.

I. To avoid the delay, expense, inconvenience, and uncertainty of litigating the above-referenced claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-I set forth above are fully adopted herein.

2. For purposes of this Agreement, "Covered Conduct" shall mean the followings:

   i. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b); and

ii. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA and DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5).

3. Morris & Dickson shall pay to the United States the total sum of TWENTY-TWO MILLION U.S. DOLLARS ($22,000,000.00) (the "Settlement Amount"), within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to Morris & Dickson by the United States Attorney's Office for the Western District of Louisiana. Failure of Morris & Dickson to pay the Settlement Amount as set forth herein will void this Agreement and, in such an event, the United States may pursue any and all available remedies against Morris & Dickson for any of the Covered Conduct herein.

4. In consideration of the undertakings by Morris & Dickson contained herein, and subject to the exceptions in Paragraph 5 below (concerning excluded claims), and conditioned upon Morris & Dickson's full payment of the Settlement Amount within the requisite time frame, the United States agrees to:

(i) Fully and finally release Morris & Dickson from any and all civil penalty claims under 21 U.S.C. § 842, as well as any and all claims for injunctive relief under 21 U.S.C. § 843, that the United States could have asserted, or may assert in the future, against Morris & Dickson related to the Covered Conduct; and

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. §842 or any action for injunctive relief under 21 U.S.C. §843 against Morris & Dickson or any of its

subsidiaries, affiliates, predecessors, successors, parent companies, and assigns of each, based on, arising from, or related to the Covered Conduct.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, the United States specifically reserves and does not release:

i. Any administrative action by the DEA based on or related to the Covered Conduct, but which does not solicit or impose civil penalties;

ii. Any federal criminal liability;

iii. Any criminal, civil or administrative claim arising under Title 26, United States Code (Internal Revenue Code);

iv. Any liability under the False Claims Act, 31 U.S.C. §3729 or the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812;

v. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and/or

vi. Any liability based on obligations created by this Agreement.

6. In consideration of the undertakings of the United States contained herein, Morris & Dickson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that Morris & Dickson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that Morris & Dickson reserves and does not release any liability based on obligations created by this Agreement. Morris & Dickson also reserves and does not release any liability based on the appointment and removal of administrative law judges under the CSA and the regulations

promulgated thereunder, unless and until such action becomes moot by the termination of the DEA Administrative Proceeding (18-31).

7. Nothing in the Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue law, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

9. Each Party shall bear its own legal or other costs incurred in connection with this matter, including the preparation, execution and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. Each Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties will be the United States District Court for the Western District of Louisiana, Shreveport Division.

12. For the purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written

Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

14. The undersigned individuals represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

15. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form or signature, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Morris & Dickson and its successors, transferees, heirs, and assigns.

17. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

18. This Agreement shall be effective (final and binding) on the date of signature by the last signatory to the Agreement (the "Effective Date" of this Agreement).

[Signatures to begin on next page]

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

DATED: May 9, 2019

Paul Dickson, CEO
Morris & Dickson Company, LLC

DATED: _____, 2019

Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By: _____ DATED: May 10, 2019

David C. Joseph
United States Attorney
Western District of Louisiana

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: _____, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: 10 May, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By:_____ DATED: _____, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

M&D Exh. 3 - AL BOP Order to Show Cause

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MORRIS & DICKSON CO, L.L.C.	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 193240	)	**CASE NO: 20-L-0013**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Morris & Dickson Co, L.L.C.
P.O. Box 51367
Shreveport, Louisiana 71135

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on August 17, 2021 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Morris & Dickson Co, L.L.C. (MDC) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that MDC has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

6. Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein.

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this State based upon the DEA suspending your Controlled Substances Registration and/or the Settlement Agreement between you and the United States attached hereto as Exhibit "A", to include but not limited to, what is described as "Covered Conduct" in the referenced Settlement Agreement.

At the aforesaid time and place and from time to time thereafter as may be

directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 29th day of March, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT "A"

CIVIL SETTLEMENT AGREEMENT

This Civil Settlement Agreement ("Civil Settlement Agreement") is entered by and between the United States Attorney's Office for the Western District of Louisiana ("USAO"), acting on behalf of the United States Department of Justice and the United States Drug Enforcement Administration ("DEA") (collectively referred to as the "United States") and Morris & Dickson Company, LLC ("Morris & Dickson") (each a "Party" and collectively the "Parties").

RECITALS

A. Morris & Dickson owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II – V controlled substances under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 et seq. (Controlled Substances Act or "CSA") (each a "Distribution Center" and collectively the "Distribution Centers").

B. In determining whether to register an applicant to distribute Schedule II – V controlled substances, the Attorney General, acting through the DEA, must consider the applicant's maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels. 21 U.S.C. §823(b)(1) and (e)(1).

C. Section 1301.74(b) of Title 21 of the Code of Federal Regulations requires registrants to operate a system to identify suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered.

D. Morris & Dickson acknowledges that its DEA-registered distribution centers were and are required to comply with the CSA and the regulations promulgated thereunder, including the requirement described in Paragraph C.

E. The DEA, by its Administrator, has pending an Order to Show Cause for Morris & Dickson to appear and show cause why the DEA registration of Morris & Dickson should not be revoked. *See In the Matter of Morris & Dickson Co., LLC*, DEA Administrative Court Docket No. 18-31.

F. In parallel to the DEA Administrative Proceeding set forth in Paragraph E, the United States Attorney's Office for the Western District of Louisiana conducted a civil investigation with the assistance of the DEA's New Orleans Field Division into alleged failures by Morris & Dickson to inform the DEA of suspicious orders of controlled substances as required by 21 C.F.R. § 1301.74(b).

G. The United States contends that Morris & Dickson failed to inform the DEA of suspicious orders as required by 21 C.F.R. §1301.74(b). The United States further contends that these violations subject Morris & Dickson to civil penalties under 21 U.S.C. §§842(a)(5) and (c)(1), as well as injunctive relief under 21 U.S.C. §843(f).

H. This Settlement Agreement is neither an admission of liability by Morris & Dickson nor a concession by the United States that its claims are not well founded.

I. To avoid the delay, expense, inconvenience, and uncertainty of litigating the above-referenced claims, and in consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Paragraphs A-I set forth above are fully adopted herein.

2. For purposes of this Agreement, "Covered Conduct" shall mean the followings:

   i. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. § 1301.74(b); and

ii. Failure, between January 1, 2014 and March 8, 2019, by Morris & Dickson to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. § 1301.74, including the failure to make records and reports required by the CSA and DEA's regulations for which a penalty may be imposed under 21 U.S.C. § 842(a)(5).

3. Morris & Dickson shall pay to the United States the total sum of TWENTY-TWO MILLION U.S. DOLLARS ($22,000,000.00) (the "Settlement Amount"), within ten (10) business days after the Effective Date of this Agreement by electronic funds transfer pursuant to the written instructions provided to Morris & Dickson by the United States Attorney's Office for the Western District of Louisiana. Failure of Morris & Dickson to pay the Settlement Amount as set forth herein will void this Agreement and, in such an event, the United States may pursue any and all available remedies against Morris & Dickson for any of the Covered Conduct herein.

4. In consideration of the undertakings by Morris & Dickson contained herein, and subject to the exceptions in Paragraph 5 below (concerning excluded claims), and conditioned upon Morris & Dickson's full payment of the Settlement Amount within the requisite time frame, the United States agrees to:

(i) Fully and finally release Morris & Dickson from any and all civil penalty claims under 21 U.S.C. § 842, as well as any and all claims for injunctive relief under 21 U.S.C. § 843, that the United States could have asserted, or may assert in the future, against Morris & Dickson related to the Covered Conduct; and

(ii) Refrain from filing any action for civil penalties under 21 U.S.C. §842 or any action for injunctive relief under 21 U.S.C. §843 against Morris & Dickson or any of its

subsidiaries, affiliates, predecessors, successors, parent companies, and assigns of each, based on, arising from, or related to the Covered Conduct.

5. Notwithstanding the release given in Paragraph 4 of this Agreement, the United States specifically reserves and does not release:

i. Any administrative action by the DEA based on or related to the Covered Conduct, but which does not solicit or impose civil penalties;

ii. Any federal criminal liability;

iii. Any criminal, civil or administrative claim arising under Title 26, United States Code (Internal Revenue Code);

iv. Any liability under the False Claims Act, 31 U.S.C. §3729 or the Program Fraud Civil Remedies Act, 31 U.S.C. § 3801-3812;

v. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and/or

vi. Any liability based on obligations created by this Agreement.

6. In consideration of the undertakings of the United States contained herein, Morris & Dickson fully and finally releases the United States, its agencies, officers, employees, servants, and agents from any claims (including attorney's fees, costs and expenses of every kind and however denominated) that Morris & Dickson has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, employees, servants, and agents related to the investigation, prosecution, and settlement of the Covered Conduct, provided, however, that Morris & Dickson reserves and does not release any liability based on obligations created by this Agreement. Morris & Dickson also reserves and does not release any liability based on the appointment and removal of administrative law judges under the CSA and the regulations

promulgated thereunder, unless and until such action becomes moot by the termination of the DEA Administrative Proceeding (18-31).

7. Nothing in the Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue law, Title 26 of the United States Code.

8. This Agreement binds and is intended to benefit only the Parties. This Agreement is not intended to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

9. Each Party shall bear its own legal or other costs incurred in connection with this matter, including the preparation, execution and performance of this Agreement.

10. Each Party and signatory to this Agreement represents that he, she or it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. Each Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties will be the United States District Court for the Western District of Louisiana, Shreveport Division.

12. For the purposes of construing this Agreement, the Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement. Each of the Parties expressly agrees and acknowledges that, in entering this Agreement, it is relying on only the statements and promises expressly set forth in this written

Agreement. This Agreement cannot be amended, nor any provisions waived, except in writing and when signed by all Parties to this Agreement.

14. The undersigned individuals represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties listed below.

15. This Agreement may be executed in counterparts, including by facsimile, pdf, or other electronic form or signature, each of which constitutes an original and all of which constitute one and the same Agreement.

16. This Agreement is binding on Morris & Dickson and its successors, transferees, heirs, and assigns.

17. The Parties may disclose the existence of and information about this Agreement to the public without restriction.

18. This Agreement shall be effective (final and binding) on the date of signature by the last signatory to the Agreement (the "Effective Date" of this Agreement).

[Signatures to begin on next page]

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: May 9, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: _____, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By: _____ DATED: May 10, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

ON BEHALF OF MORRIS & DICKSON COMPANY, LLC

_____ DATED: _____, 2019
Paul Dickson, CEO
Morris & Dickson Company, LLC

_____ DATED: 10 May, 2019
Jodi Avergun
Cadwalader, Wickersham & Taft, LLP
Counsel for Morris & Dickson Company, LLC

ON BEHALF OF THE UNITED STATES

By:_____ DATED: _____, 2019
David C. Joseph
United States Attorney
Western District of Louisiana

M&D Exh. 4 - Kentucky BOP Letter of Concern

ANDY BESHEAR
GOVERNOR

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort, Kentucky 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

BOARD MEMBERS
JASON BELCHER, CONSUMER
PETER P. COHRON, R.PH.
MEREDITH FIGG, PHARM.D.
ANTHONY TAGAVI, PHARM.D.
JOHN FULLER, R.PH.
JONATHAN VAN LAHR, R.PH.

EXECUTIVE DIRECTOR
CHRISTOPHER P. HARLOW, PHARM D.

February 7, 2022

Morris and Dickson, LLC
10301 HWY 1 South
Shreveport, Louisiana 71115
License: W02005

RE: LETTER OF CONCERN, 18-0364

Dear Permit Holder:

At its January 19, 2022, meeting, the Board of Pharmacy's Case Review Panel, comprised of three board members, considered a grievance alleging that you entered a Settlement Agreement with the United States government to pay civil penalty claims and to invest in significant upgrades to your compliance program for allegedly violating the Controlled Substances Act by failing to report suspicious orders of hydrocodone and oxycodone by pharmacies. From the period of January 2014 through April 2018, there were eleven suspicious orders by three Kentucky pharmacies. The Panel reviewed the case report, Settlement Agreement, policies and procedures prior to the Settlement Agreement, and policies and procedures after the Settlement Agreement.

Having considered all the information available and being sufficiently advised, the Panel found that there is insufficient evidence of a violation to warrant the issuance of a Complaint, but that there is evidence of a practice or activity that requires modification. The Panel expressed concern regarding the Settlement Agreement and its relation to the suspicious orders of hydrocodone and oxycodone to three Kentucky pharmacies, which would qualify as a violation of KRS 315.121 (1)(c)2. The Panel determined that this letter of concern be issued.

Sincerely,

Peter P. Cohron
President
Kentucky Board of Pharmacy

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Genentech, Inc.
Address: 1 DNA Way City: South San Francisco State: CA Zip: 94083

Name: Bristol Myers Squibb
Address: 4931 George Road City: Tampa State: FL Zip: 33634

Name: Amgen USA, Inc.
Address: One Amgen Center Drive City: Thousand Oaks State: CA Zip: 91320

Name: Ipsen Biopharmaceuticals, Inc.
Address: 106 Allen Road City: Basking Ridge State: NJ Zip: 40118

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Louisiana
Parent Company (if any): N/A
Corporation/Organization Name: M&D Specialty Distribution, L.L.C.
Mailing Address: P.O. Box 5145
City: Shreveport State: LA Zip: 71135
Telephone: 800-710-6100 Email: licensing@mdspecialtydist.com
Contact Person Name: Scott Irelan

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

M&D Specialty Distribution, L.L.C.

Facility Name

Paul M Dickson Jr

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/22/2023

Date

Board Use Only	Date Received: 11/28/23	Amount: $1,000 Check 005627

NABP ACCREDITED
DRUG DISTRIBUTOR

M&D Specialty Distribution, L.L.C.

located at

10301 Hwy 1 South, Shreveport, LA 71115

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/21/2021 - 12/20/2024
Period of Accreditation

M&D Specialty Distribution, L.L.C.
Ownership List

Name / Entity	Sharing Ratio
WLDT No. 2, L.L.C.	11.1111%
WGDT No. 2, L.L.C.	11.1111%
MADT No. 2, L.L.C.	11.1111%
Jacob Allen Dickson	8.3333%
Paul Meade Dickson, Jr.	8.3333%
Russell Reginald Dickson	8.3333%
Clayton Rigby Dickson	8.3333%
C.M. Dickson No. 1 Limited Partnership	8.3333%
C.M. Dickson No. 2 Limited Partnership	8.3333%
C.M. Dickson No. 4 Limited Partnership	8.3333%
C.M. Dickson No. 5 Limited Partnership	8.3333%
	100.000%

M&D Specialty Distribution, L.L.C.
Officers & Directors

Officers listed as "of MD" are officers of Morris & Dickson Co., L.L.C. ("MD"), which performs operational services for M&D Specialty Distribution, L.L.C. ("MDSD") pursuant to contract.

Name	Information
Jody McLendon Hatcher, CEO of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Paul Meade Dickson, Jr., COO of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Clayton Rigby Dickson, Vice President of MD & Manager of MDSD	Business address: 410 Kay Ln., Shreveport, LA 71115
Jeffrey Scott Irelan, Director of Compliance of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Braden Hunter, CFO of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Jason Hanks, Chief Commercial Officer of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Krista Tongring, Interim Chief Compliance Officer of MD	Business address: 410 Kay Ln., Shreveport, LA 71115
Markham A. Dickson, III, Manager of MDSD	Business address: 410 Kay Ln., Shreveport, LA 71115
Michael Chenu Palmer Dickson, Manager of MDSD	Business address: 410 Kay Ln., Shreveport, LA 71115

UNITED STATES OF AMERICA

State of Louisiana

R. Kyle Ardoin

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

M&D SPECIALTY DISTRIBUTION, L.L.C.

A limited liability company domiciled in SHREVEPORT, LOUISIANA,

Filed charter and qualified to do business in this State on June 26, 2014,

I further certify that the records of this Office indicate the company has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned, is in good standing and is authorized to do business in this State.

I further certify that this certificate is not intended to reflect the financial condition of this company since this information is not available from the records of this Office.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

September 14, 2023

Secretary of State

Web 41565497K

Certificate ID: 11783274#5PK73

To validate this certificate, visit the following web site, go to **Business Services**, **Search for Louisiana Business Filings**, **Validate a Certificate**, then follow the instructions displayed.
www.sos.la.gov

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

SUB-TYPES: Standard Distributor, Wholesale Distributor, Third-Party Logistic Provider Distributor

M & D SPECIALTY DISTRIBUTION LLC

License No. **8068** effective **01/01/2024** *(Original issue date: 09/11/2014)*, Expiring **12/31/2024**
distributing from **10301 Highway 1 South, Suite 200, Shreveport, LA, 71115**
BUSINESS ADDRESS: 410 KAY LANE, SHREVEPORT, LA, 71115
is duly licensed in the State of Louisiana with this Board under the provisions of Act 852 of 1988 (as amended).
This license is subject to regulation in the state of Louisiana
in accordance with La. R.S. 37:3461 through 3482 and LAC 46:XXXIV.101 through 1503.

Additional Third-Party Logistics Providers:
NA

Board Secretary

ORIGINAL LICENSE — DISTRIBUTOR
This License is NOT TRANSFERABLE and must be Conspicuously Displayed. This license must be renewed annually

Louisiana Board of Drug and Device Distributors 12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816	Phone: (225) 295-8567 Fax: (225) 295-8568	www.drugboard.la.gov Email: admin@drugboard.la.gov

SUB-TYPES:

Standard Distributor: Any entity that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

Wholesale Distributor: Any entity that sales or facilitates the delivery of drug product (as defined by FDA) to persons other than the consumer or patient; not to include (not limited to) manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

Third-party Logistics Provider: Any entity that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/31/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Arthur J. Gallagher Risk Management Services, LLC
470 Ashley Ridge Boulevard
Shreveport LA 71106

CONTACT NAME: Myriam Victoria
PHONE (A/C, No, Ext): 318-629-8125 FAX (A/C, No): 318-798-5507
E-MAIL ADDRESS: Myriam_Victoria@ajg.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Bridgefield Casualty Insurance Company	10335
INSURER C : Everspan Indemnity Insurance Company	16882
INSURER D : General Star Indemnity Company	37362
INSURER E : Technology Insurance Company, Inc	42376
INSURER F :	

INSURED
MORRIS & DICKSON CO., LLC
P. O. Box 51367
Shreveport, LA 711351367

COVERAGES **CERTIFICATE NUMBER:** 114546421 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDC G47347026	9/1/2023	9/1/2024	EACH OCCURRENCE	$ 10,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 5,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			ISA H10751615	9/1/2023	9/1/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
C	UMBRELLA LIAB X OCCUR			QM1EII-000239-01	9/1/2023	9/1/2024	EACH OCCURRENCE	$ 2,000,000
	X EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$ 2,000,000
	DED RETENTION $						Excess Auto Only	$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			0196-58739	9/1/2023	9/1/2024	X PER STATUTE OTH-ER	
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N/A			19900022	9/1/2023	9/1/2024	E.L. EACH ACCIDENT	$ 1,000,000
E	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			TWC4306574	9/1/2023	9/1/2024	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
D	Excess Auto Liability			IXG677426	9/1/2023	9/1/2024	Each Occurrence Aggregate	$2,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Certificate holder is included as Additional Insured on the General Liability policy, as per endorsement # CG 20 26, Edition (04/13) and Auto Liability policy, as per endorsement #CA990187, edition (07/15).
Waiver of Subrogation applies to certificate holder, as respects to the General Liability & Auto Liability policies, pursuant to and subject to the policy's terms, definitions, conditions and exclusions.

Excess Liability is Excess of Primary Auto Liability only.

CERTIFICATE HOLDER

FOR INFORMATION ONLY

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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JPMORGAN CHASE BANK, N.A.
TRADE & WORKING CAPITAL
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128
SWIFT: CHASUS33

To:
M AND D Specialty Distribution, LLC
10301 Highway 1 South, Suite 200
Shreveport, Louisiana, 71115

Date: 10 Nov 2023
Subject : Acknowledgement Advice for Standby Letter of Credit
Our Reference : NUSCGS049477

Dear Sir/Madam,

Your Reference	:	NEVADA STATE BD
Standby LC Reference	:	NUSCGS049477
Account Party	:	M AND D Specialty Distribution, LLC 10301 Highway 1 South, Suite 200 Shreveport, LA 71115
Beneficiary	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206, RENO, NV 89521 ATTN: EXECUTIVE SECRETARY

As per your request we have issued our Irrevocable Standby Letter of Credit in the favor of beneficiary under our reference number stated above.

We hereby enclose the copy of the Irrevocable Standby Letter of Credit for your information and record purpose.

We have debited your USD account XXXXX3288 for value 10 Nov 2023 as detailed herein:

Standby LC Issuance Fee : USD 750.00

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS049477 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,

Authorized Signature
Ralph Davis
VP - Operations Manager

Continuation of our Reference NUSCGS049477

Continuation of our Reference NUSCGS049477

COPY OF STANDBY LETTER OF CREDIT ISSUED

DATE : 10 Nov 2023

IRREVOCABLE STANDBY LETTER OF CREDIT REFERENCE NO.: NUSCGS049477

TO: NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY,
SUITE 206, RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

DEAR SIR/MADAM,

WE HEREBY ISSUE OUR IRREVOCABLE STANDBY LETTER OF CREDIT IN YOUR FAVOR.

BENEFICIARY	:	NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206, RENO, NV 89521 ATTN: EXECUTIVE SECRETARY
ACCOUNT PARTY	:	M AND D SPECIALTY DISTRIBUTION, LLC 10301 HIGHWAY 1 SOUTH, SUITE 200 SHREVEPORT, LA 71115
DATE OF EXPIRY	:	30-SEP-2024
PLACE OF EXPIRY	:	OUR COUNTER
AMOUNT	:	USD 25,000.00
APPLICABLE RULE	:	ISP LATEST VERSION

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF M AND D SPECIALTY DISTRIBUTION, LLC, WE JPMORGAN CHASE BANK, N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF USD 25,000.00 (TWENTY FIVE THOUSAND AND 00/100 U.S. DOLLARS) .

2. WE UNDERSTAND THAT THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE ACCOUNT PARTY/LICENSEE.

3. WE FURTHER UNDERSTAND THAT THIS CREDIT IS INTENDED TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY ACCOUNT PARTY/ LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING ACCOUNT PARTY/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN SUBSTANTIALLY THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS BELOW.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE BY REGISTERED MAIL, RETURN RECEIPT REQUESTED, OR COURIER.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL SEND THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFOR, AND RETURN THE DOCUMENTS TO THE BOARD.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED IN WHOLE OR IN PART ONLY UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED, EITHER IN WHOLE OR IN PART.

14. THIS CREDIT SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA AND INTERNATIONAL STANDBY PRACTICES, 1998, I.C.C. PUBLICATION NO. 590 ('ISP98'). AS TO THE MATTERS NOT COVERED BY ISP98, SHALL BE SUBJECT TO LAWS OF THE STATE OF NEVADA.

PLEASE ADDRESS ALL CORRESPONDENCE REGARDING THIS STANDBY LETTER OF CREDIT QUOTING OUR REFERENCE USCGS049477 TO:
JPMORGAN CHASE BANK, N.A.
ATTN: TRADE OPERATIONS - STANDBY LCS
10410 HIGHLAND MANOR DRIVE, FLOOR 03
TAMPA, FL 33610-9128

Continuation of our Reference NUSCGS049477

All inquiries regarding this transaction may be directed to our Client Service Group quoting our reference NUSCGS049477 using the following contact details:
Telephone Number: 1-800-634-1969
Email Address: gts.client.services@jpmchase.com

Yours Faithfully,
JPMorgan Chase Bank, N.A.,

Authorized Signature
Ralph Davis
VP - Operations Manager

END OF COPY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: M&D Specialty Distribution, L.L.C. MDEG License # (if applicable): N/A

Physical Address: 10301 Highway 1 South, Suite 200

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 5145

City: Shreveport State: LA Zip: 71135

Telephone: 800-710-6100 Website: www.morrisdickson.com/md-specialty-distribution

Licensing Company Email: licensing@mdspecialtydist.com

Section 2: Personal Information

First: Alan Middle: Wayne Last: Bass

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITI[redacted] Sex ☑ M ☐ F ☐ X

Mailing Add[redacted]

City: Shreveport State: LA Zip: 71135

Telephone: 318-797-7900 Email: licensing@mdspecialtydist.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Huntington High School		08/1979 - 05/1982	
Address	**City**	**State**	**Zip**
6801 Rasberry Lane	Shreveport	LA	71129
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2007-Present	[redacted]	Grand Cane	LA	71032
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: M&D Specialty Distribution, LLC			From - To (MM/YY – MM/YY): 08/1990 - Present
Business Address: 10301 Highway 1 South, Suite 200	City: Shreveport	State: LA	Zip: 71115
Phone: 318-797-7900	Title: Special Projects Manager		Number of Employed Hours: 67,766.40
Description of Duties: Please see attached list of duties.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Alan Bass

Daily Duties

- Daily over sight of the Inventory crew and all their duties.
- Making sure all products are in the best picking location for the flow of orders through the DC.
- Working with A/P to find and correct receiving errors.
- Working with customer service and sales team to stop damage to product during the order filling process, shipping and any other issues they may have.
- Tracking expiration dates on all items, working purchasing on pulling expired items.
- Manage Covid vaccine area, LDH K-12 Covid testing program and Federal N95 mask program.
- Find recyclers for EPS, plastic bales and other material to keep it from going to the landfill. Work on SOPs and P&Ps for the DC.
- Monitor M&D DC, MDSD and MDT temperatures. Manage ongoing projects at DC.
- Keep DC AutoCAD updated.
- Assist with the selection and planning of DC automation, AS/RS and carousels.
- Work with box and sack venders keeping the DC stocked with both.
- Work with production team and reassign Inventory crew to help with production when needed.
- CDR for MDSD.
- Working with Compliance Department on state licenses

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-17-23
Date

I, Alan Bass, **certify that as the MDEG Administrator for**

M&D Specialty Distribution, L.L.C.,

that I (initial that you have read and meet the following requirements):

1. AB Have a high school diploma or its equivalent;
2. AB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alan Bass
Print Name (First, Last)

Alan Bass
Original Signature (electronic, copies or stamps not accepted)

11-17-23
Date

Board Use Only	Date Received: 11/28/23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: M&D Specialty Distribution, L.L.C.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 10301 Highway 1 South, Suite 200

City: Shreveport State: LA Zip: 71115

Mailing Address (if different from physical address): P.O. Box 5145

City: Shreveport State: LA Zip: 71135

Telephone: 800-710-6100 Website: www.morrisdickson.com/md-specialty-distribution

Licensing Company Email: licensing@mdspecialtydist.com

Section 2: Personal Information

First: Alan Middle: Wayne Last: Bass

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Addr[redacted]

City: Shreveport State: LA Zip: 71135

Telephone: [redacted] Email: licensing@mdspecialtydist.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Huntington High School		08/1979-05/1982	
Address	City	State	Zip
6801 Rasberry Lane	Shreveport	LA	71129
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2007 - Present	[redacted]	Grand Cane	LA	71032
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Morris & Dickson Co., L.L.C.			08/1990- Present	
Business Address		**City**	**State**	**Zip**
10301 Highway 1 South		Shreveport	LA	71115
Phone	**Title**		**Number of Employed Hours**	
318-797-7900	Special Projects Manager		67,766.40	
Description of Duties				
Please see attached.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Alan Bass

Daily Duties

- Daily over sight of the Inventory crew and all their duties.
- Making sure all products are in the best picking location for the flow of orders through the DC.
- Working with A/P to find and correct receiving errors.
- Working with customer service and sales team to stop damage to product during the order filling process, shipping and any other issues they may have.
- Tracking expiration dates on all items, working purchasing on pulling expired items.
- Manage Covid vaccine area, LDH K-12 Covid testing program and Federal N95 mask program.
- Find recyclers for EPS, plastic bales and other material to keep it from going to the landfill. Work on SOPs and P&Ps for the DC.
- Monitor M&D DC, MDSD and MDT temperatures. Manage ongoing projects at DC.
- Keep DC AutoCAD updated.
- Assist with the selection and planning of DC automation, AS/RS and carousels.
- Work with box and sack venders keeping the DC stocked with both.
- Work with production team and reassign Inventory crew to help with production when needed.
- CDR for MDSD.
- Working with Compliance Department on state licenses

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 & 6 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

**********Questions 5 & 6 were both answered no, as Alan Bass, the Designated Representative, is not associated with the business as an owner, partner, member, officer, or director. A narrative was provided by the company, and certain owners, listing administrative proceedings.**********

Alan Bass
Original Signature (electronic, copies or stamps not accepted)

11-17-23
Date

I, Alan Bass, **certify that as the designated representative for**

M&D Specialty Distribution, L.L.C.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alan Bass

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-17-23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alan Bass

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-17-23

Date

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of Caddo Parish

I, Alan Wayne Bass, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-17-23

Date

Subscribed and Sworn to before me this 17th day of November

Notary Public Signature

Shannon Moffett
Caddo Parish, Louisiana
Notary Public
Commission No. 179902
My Commission Expires Upon Death

(Seal)

M & D Specialty Distribution, L.L.C. ("MDSD") has no employees. Labor to MDSD is supplied through a contract with Morris & Dickson Co., L.L.C.

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816
(225)295-8567 (225)295-8568 admin@drugboard.la.gov www.drugboard.la.gov

INSPECTION REPORT - Page 1 of 4

License / Application #:	8068	**Inspection Date:**	11/30/2022
Licensed Facility Name:	M & D SPECIALTY DISTRIBUTION LLC	**License Type:**	W
Facility Address:	10301 Highway 1 South	**Product:**	LD, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

Facility Changes Since Last Inspection?			Outstanding Violations?			Previous Thefts or Losses of Product?		
Yes	No	N/A	Yes	No	N/A	Yes	No	N/A
	N			N			N	

		Yes	No	N/A	Comments
1.	Is DRP available for inspection or on authorized leave/absence? [LAC 46:XXXIV.305.D.1.e]	Y			
2.	Current LBDDD license displayed [LAC 46:XXXIV.301.G]	Y			
3.	Has off-site storage facility (ies) [LAC 46:XXXIV.301.K]		N		
4.	Facility is of suitable size and Construction [LAC 46:XXXIV.309.A.1.a]	Y			
5.	Facility is clean and orderly [LAC 46:XXXIV.309.A.1.d]	Y			
6.	Facility is free from infestation by insects, rodents, birds, or vermin of any kind [LAC 46:XXXIV.309.A.1.e]	Y			No evidence of infestation
7.	Storage provides adquate: [LAC 46:XXXIV.309.A.1.b]				
	a. Lighting	Y			
	b. Ventilation	Y			
	c. Temperature	Y			
	d. Sanitation	Y			
	e. Humidity	Y			
	f. Space	Y			
	g. Equipment	Y			
	h. Security Conditions	Y			
8.	Storage area has a designated and clearly identified quarantine area for storage of drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened [LAC 46:XXXIV.309.A.1.c]	Y			Quarantine sign
9.	Storage facility has a working monitored alarm system or (medical gas only) is a board approved facility kept under lock and key [LAC 46:XXXIV.309.A.2.b&c]	Y			Centurylink
10.	Medical Gases only distributors that store medical gases on an open dock shall be equipped with a monitored alarm system [LAC 46:XXXIV.309.A.2.d]			N/A	No medical gases

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INSPECTION REPORT - Page 2 of 4

License / Application #:	8068	**Inspection Date:**	11/30/2022
Licensed Facility Name:	M & D SPECIALTY DISTRIBUTION LLC	**License Type:**	W
Facility Address:	10301 Highway 1 South	**Product:**	LD, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

		Yes	No	N/A	Comments
11.	Facility equipped with monitored security system suitable for protection againt theft or diversion and provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records [LAC 46:XXXIV.309.A.2.e]	Y			
12.	Drug or Device products are stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or devices or in compliance with an official compendium [LAC 46:XXXIV.309.A.3]	Y			
13.	Facility utilizes appropriate electromechanical or electronic temperature recording equipment, devices, and logs approved by the LBDDD [LAC 46:XXXIV.309.A.3.b]	Y			
14.	Inventory records readily available for inspection for three years following disposition of the drugs or devices at issue [LAC 46:XXXIV.311.A&C]	Y			
15.	Financial records readily available for inspection for three years from the date each record was created [LAC 46:XXXIV.311.B]			N/A	
16.	Perpetual inventories and records maintained of all transactions regarding the receipt, distribution, or other disposition for all drugs, devices, and or medical gases are current [LAC 46:XXXIV.311.A]	Y			
17.	Temperature monitoring logs are maintained and current (excluding medical gasses only) [LAC 46:XXXIV.309.A.3.b]	Y			Sonic "U" digital monitoring
18.	Copies of customer licenses verifying authority to procure or possess drug products or devices on file and current or if maintained off site, a copy of the customer list [LAC 46:XXXIV.311.E]	Y			
19.	Has verified all suppliers are licenced by LBDDD [LAC 46:XXXIV.311.G]	Y			
20.	Has established and maintains policies and procedure [LAC 46:XXXIV.313]	Y			
	a. Receipt of drug, devices and/or medical gases [LAC 46:XXXIV.313.A]	Y			
	b. Storage [LAC 46:XXXIV.313.A]	Y			
	c. Security [LAC 46:XXXIV.313.A]	Y			
	d. Inventory [LAC 46:XXXIV.313.A]	Y			
	e. Distribution [LAC 46:XXXIV.313.A]	Y			
	f. Correction of inventory errors and inaccuracy [LAC 46:XXXIV.313.A]	Y			
	g. Inspection of all incoming & outgoing shipments [LAC 46:XXXIV.313.A.5]	Y			

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INSPECTION REPORT - Page 3 of 4

License / Application #:	8068	**Inspection Date:**	11/30/2022
Licensed Facility Name:	M & D SPECIALTY DISTRIBUTION LLC	**License Type:**	W
Facility Address:	10301 Highway 1 South	**Product:**	LD, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

		Yes	No	N/A	Comments
	h. Product rotation to ensure distribution of oldest approved stock [LAC 46:XXXIV.313.A.1]	Y			
	i. Recalls and withdrawals [LAC 46:XXXIV.313.A.2]	Y			
	j. Out-dated drug or device segregation; Return or destruction; 3-year record retention [LAC 46:XXXIV.313.A.4]	Y			
	k. Validation of customer licenses [LAC 46:XXXIV.313.A.5]	Y			
	l. Notification within 3 business days of theft or diversion [LAC 46:XXXIV.313.A.6]	Y			
	m. Preparation and protection against any crisis that affects security or operation of facility in event of strike, fire, flood, or other situations of local, state, or national emergency [LAC 46:XXXIV.313.A.3]	Y			
	n. Notification within 24 hours of discovery of contraband, counterfeit or misbranded drugs [LAC 46:XXXIV.313.A.7]	Y			
	o. Verification of suppliers [46:XXXIV.311.G]	Y			
	p. Review of excessive or suspicious purchases [LAC 46:XXXIV.313.A.5]	Y			
	q. Monitoring & recording of storage temperatures [LAC 46:XXXIV.313.A.5]	Y			
21.	Maintains on-site current list of responsible persons, owners, officers, directors, manager, and designated responsible party [LAC 46:XXXIV.315.A]	Y			
	a. List of employees with access to product	Y			
	b. List of employees with access to building after hours	Y			
22.	Facilities handling controlled substances				
	a. Has current CDS registration.			N/A	
	b. Has current DEA registration.			N/A	
	c. Arcos reports submitted.			N/A	
	d. Suspicious Excessive reports submitted.			N/A	

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INSPECTION REPORT - Page 4 of 4

License / Application #:	8068	**Inspection Date:**	11/30/2022
Licensed Facility Name:	M & D SPECIALTY DISTRIBUTION LLC	**License Type:**	W
Facility Address:	10301 Highway 1 South	**Product:**	LD, DV
	Shreveport, LA 71115	**Designated Responsible Party:**	Alan Bass

Notes:
None

The signature of licensee representative only validates that an inspection took place.

Licensee Representative — Date: 11/30/2022

Inspector's Signature — Date: 11/30/2022

M&D Specialty Distribution, L.L.C.

January 16, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: M & D Specialty Distribution, L.L.C. Pending Initial Wholesale Drug Distributor Application

Dear Licensing Authority,

This letter provides information supplementing the above pending applications submitted by M&D Specialty Distribution, L.L.C. ("MDSD"), a pharmaceutical wholesaler located in Shreveport, Louisiana.

MDSD is not a distributor of controlled substances. MDSD is contractually affiliated and has overlapping ownership with Morris & Dickson Co., LLC ("M&D Co."), which also is a pharmaceutical wholesaler located in Shreveport, Louisiana. M&D Co.'s business includes the distribution of controlled substances. M&D Co. has settled an administrative proceeding with the United States Drug Enforcement Administration concerning events between 2014 and 2018 (the "2018 Proceeding"), pursuant to a Settlement and Administrative Memorandum of Agreement (the "MOA"). M&D Co. has provided a copy of the MOA to the Board. The MOA does not pertain to MDSD.

Should your agency require any additional information, please direct any inquiries regarding this matter to:

Paul Weinstein, Esq.
Outside General Counsel
Emmet, Marvin & Martin, LLP
120 Broadway, 32nd Fl.
New York, NY 10271
pweinstein@emmetmarvin.com

Thank you for your assistance in this matter,

M&D Specialty Distribution, L.L.C.

Morris & Dickson

January 16, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: Morris & Dickson Co., L.L.C., Pending Initial Wholesale Drug Distributor Application

Dear Licensing Authority,

This letter provides information supplementing the above pending applications submitted by Morris & Dickson Co., L.L.C. ("M&D Co."), a pharmaceutical wholesaler located in Shreveport, Louisiana. M&D Co. has settled an administrative proceeding with the United States Drug Enforcement Administration concerning events between 2014 and 2018 (the "2018 Proceeding"), pursuant to a Settlement and Administrative Memorandum of Agreement (the "MOA"). A copy of the MOA is attached to this letter. The 2018 Proceeding has been the subject of prior reporting to the Board. It is requested that the MOA remain confidential with the Board.

The MOA permits the full continuation of M&D Co.'s business in all respects. Terms of the MOA include a payment to the DEA and M&D's maintenance of its existing compliance policies and procedures. M&D Co. distributes controlled substances from its Shreveport, Louisiana facility pursuant to that facility's DEA registration (the "M&D Co. DEA Registration"). Pursuant to the MOA, M&D Co. maintains the M&D Co. DEA Registration.[1]

Should your agency require any additional information, please direct any inquiries regarding this matter to:

Paul Weinstein, Esq.
Outside General Counsel
Emmet, Marvin & Martin, LLP
120 Broadway, 32nd Fl.
New York, NY 10271
pweinstein@emmetmarvin.com

Thank you for your assistance in this matter,

Morris & Dickson Co., L.L.C.

---

[1] The company is surrendering a separate DEA registration for a facility in Jefferson, Louisiana, which, for in excess of the past 10 years, has been operated by M&D Co. dba Spark Drug (the "Spark Facility"), solely for the purpose of distributing non-controlled drugs to certain customers within Louisiana. Thus, the Jefferson, Louisiana DEA registration has not been used by M&D Co. for over 10 years. The surrender of the Jefferson, Louisiana DEA registration will have no effect on M&D Co.'s business. The Spark Facility is not the subject of the above-referenced pending license application(s).

January 12, 2024 Settlement and Administrative Memorandum of Agreement

SETTLEMENT AND ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Settlement and Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and Morris & Dickson Co., LLC ("M&D") (each a "Party" and collectively the "Parties").

This Agreement shall be applicable to M&D and any facility owned or operated by M&D that is registered, or that may become registered, with DEA to distribute or otherwise handle controlled substances.

I. RECITALS

1. In order to avoid the uncertainty and expense of continued litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further below, including without limitation M&D's appeal pending in the Court of Appeals for the Fifth Circuit. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of this matter.

2. M&D owns and operates (or has previously owned and operated) two (2) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances, Registration Nos. RM0314790 and RM0335732 (together the "COR") under the provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. ("CSA") (each a "Distribution Center" and collectively the "Distribution Center").

3. The DEA is the Department of Justice component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

4. The regulations promulgated under the CSA require registrants to design and operate a system to detect and report "suspicious orders" for controlled substances, as defined in the regulations. *See* 21 C.F.R. § 1301.74(b).

5. On or about May 2, 2018, DEA served M&D with an Order to Show Cause ("OTSC") and Immediate Suspension of Registration ("ISO"), immediately suspending M&D's COR, pursuant to 21 U.S.C. § 824(d), and proposing to revoke its COR and deny any pending

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applications for renewal or modification, pursuant to 21 U.S.C. §§ 824(a)(4) & 823(b).

6. On or about May 5, 2018, M&D obtained a temporary restraining order prohibiting DEA from enforcing the ISO (the "TRO").

7. On or about May 18, 2018, Acting Administrator Robert W. Patterson rescinded the ISO, but left the Order to Show Cause in place.

8. On May 13-16, 2019, DEA held an administrative hearing on the Order to Show Cause before Administrative Law Judge ("ALJ") Charles W. Dorman (the "ALJ Hearing").

9. On or about August 29, 2019, ALJ Dorman issued a Recommended Rulings, Findings of Facts, Conclusions of Law, and Decision ("R&R"). In the R&R, he recommended that both of M&D's CORs be revoked.

10. On or about May 19, 2023, Administrator Anne Milgram issued a Decision and Order ("Final Order") revoking both of M&D's CORs, effective thirty days from the Final Order's publication in the Federal Register.

11. On May 23, 2023, the Administrator modified her decision to allow M&D ninety days to attempt to reach a settlement with the Agency.

12. On or about May 30, 2023, the Final Order was published in the Federal Register.

13. On or about June 2, 2023, M&D petitioned the Court of Appeals for the Fifth Circuit for a stay of the effective date of the Final Order.

14. On or about June 16, 2023, the Fifth Circuit granted M&D's request for a full stay of the effective date of the Final Order pending a decision on the merits.

II. TERM OF AGREEMENT

15. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the effective date of this Agreement unless DEA agrees in writing to an earlier termination.

III. ACCEPTANCE OF RESPONSIBILITY

16. M&D acknowledges and unconditionally accepts responsibility for every CSA violation found by the Administrator in the Agency's Final Order (the "Covered Conduct"). See Final Order attached as **Appendix A**.

IV. COMPLIANCE ADDENDUM

17. Simultaneous with the execution of this Agreement, M&D and DEA have entered into a Compliance Addendum, which is attached as **Appendix B**.

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V. REGISTRATION CONSEQUENCES

18. M&D agrees to immediately surrender for cause its DEA Certificate of Registration No. RM0335732.

19. Following the surrender for cause of DEA Certificate of Registration No. RM0335732, M&D shall respond in the affirmative to any and all questions on Federal or State application and registration application concerning whether M&D has been subject to liability.

20. As to DEA Certificate of Registration RM0314790, M&D and DEA stipulate that:

a. Revocation of DEA Certificate of Registration RM0314790 was the proper remedy for the Covered Conduct;

b. In the period between DEA's ISO and OTSC and the Final Order, M&D expended substantial resources to remediate its compliance program.

c. DEA Certificate of Registration RM0314790 was suspended during the period between the ISO and the TRO. This suspension, together with M&D's surrender of DEA Certificate of Registration No. RM0335732, is a sufficient registration consequence considering:

i. The extended passage of time between the issuance of the ISO and the Final Order;

ii. The substantial resources M&D spent to remediate its compliance program with respect to suspicious orders and due diligence;

iii. M&D's agreement to enter a five-year Compliance Addendum;

iv. M&D's good faith anti-diversion efforts in the pre-ISO period, including its destruction (rather than sale) of $2.5 million of short-dated opioids; and

v. M&D's agreement to the payment terms set forth in this Agreement.

VI. TERMS AND CONDITIONS

21. In consideration of the mutual promises, covenants, and obligations set forth herein, DEA and M&D agree as follows:

a. M&D shall pay a total of Thirty-three Million Dollars ($33,000,000.00), which includes:

i. Fourteen Million Dollars ($14,000,000.00) of costs M&D incurred to enhance its compliance system between the date of the ISO and the present, which DEA agrees is hereby credited to the amount in paragraph

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21(a) above.

ii. M&D shall pay an additional Nineteen Million Dollars ($19,000,000.00) to DEA/Department of Justice consistent with the terms set forth below:

a) DEA will initiate administrative forfeiture proceedings against the $19 million based on the probable cause established in the May 19, 2023, Final Order executed by DEA Administrator Anne Milgram. This amount will be paid in five equal annual installments, beginning in 2025. For clarity, and as agreed by the parties, these payments totaling $19,000,000.00 are paid by M&D as remediation for M&D's alleged violations of the law resulting in alleged damage or harm.

b) Upon completion of the forfeiture proceedings, all forfeited proceeds will be disposed of according to the applicable Federal law.

c) Morris & Dickson Co., LLC waives any right to administrative or judicial notice of the forfeiture proceedings regarding the five annual payments, totaling $19 million, and further agrees to abandon and forfeit any interest they may have in each payment when made in the entirety of the $19 million once all payments are complete.

d) Each annual payment shall be made by cashier's check at the DEA New Orleans Field Division on the first business day after January 1, beginning in 2025.

c. Any material breach by M&D of this Agreement or the Compliance Addendum may be a basis upon which DEA takes administrative action against M&D. However, nothing in this Agreement shall be deemed a waiver of M&D's due process rights. Further, DEA hereby agrees to provide M&D a thirty (30) day safe harbor period to allow M&D the opportunity to cure any alleged breach before it initiates any administrative action.

d. In consideration of the fulfillment of the obligations of M&D under this Agreement, DEA agrees to:

1/12/24

i. Fully and finally release M&D, together with its parent and subsidiary entities, facilities, registrants, officers, directors, employees, successors, attorneys, assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct through December 31, 2021, which the DEA asserted, or could have asserted based upon information that was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the effective date of this Agreement, and the review of the reports and records of M&D submitted to DEA prior to the effective date of this Agreement; and

ii. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct, provided that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the effective date of this Agreement, and the review of the reports and records of M&D submitted to DEA prior to the effective date of this Agreement. This Release applies only to administrative actions brought before or by DEA with respect to the Covered Conduct.

e. M&D fully and finally releases DEA from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which M&D has asserted, could have asserted, or may assert in the future against DEA related to the Covered Conduct and DEA's investigation and prosecution thereof, including without limitations M&D's appeal pending before the Court of Appeals for the Fifth Circuit and its action pending against DEA in U.S. District Court for the Western District of Louisiana.

22. Except as expressly set forth herein, there are no additional promises, understandings, or agreements between M&D and DEA concerning any other administrative proceeding relating to any other federal, state, or local charges that may now be pending or hereafter be brought against M&D. Nor may any additional agreement, understanding, or

1/12/24

condition relating to the Covered Conduct be entered into by M&D and DEA unless in writing and signed by both. However, the Parties acknowledge and agree that nothing herein conflicts with or modifies a separate nonprosecution agreement anticipated between M&D and the Department of Justice.

VII. MISCELLANEOUS

23. Binding on Successors. This Agreement is binding on M&D, and its respective successors, heirs, transferees, and assigns.

24. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

25. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

26. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transaction contemplated by this Agreement. M&D represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. M&D further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

27. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). DEA agrees to notify M&D immediately when the final signatory has executed this Agreement.

28. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, VA 22152; and

1/12/24

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.

b. For M&D:

Chief Compliance Officer
Morris & Dickson Co., LLC
410 Kay Lane
Shreveport, LA 71115

29. Disclosure. M&D and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

30. Confidentiality and Designation of Information. M&D and DEA agree that all reports submitted to DEA contain information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under FOIA and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide M&D reasonable opportunity to respond to any such requests.

31. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimile of signatures shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

32. Authorizations. The individuals signing this Agreement represent and warrant that they are authorized to execute his Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

33. Choice of Law and Venue. This Agreement shall be construed in accordance with the laws of the United States, and either party may seek judicial enforcement of this Agreement upon a material breach by the other party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

1/12/24

34. Reservation of Rights: Nothing in this Agreement in any way limits, or is intended to limit, M&D's defenses against liability, based on factual or legal defenses, in any other pending or future litigation, other than in an action by DEA to enforce this Agreement.

35. M&D Standard Operating Procedures: M&D agrees to update its current Standard Operating Procedures to reflect the agreements herein.

IN WITNESS WHEREOF, M&D and DEA hereto have duly executed this Agreement by their authorized representatives.

Date: January 12, 2024

By

THOMAS PREVOZNIK

Digitally signed by THOMAS PREVOZNIK
Date: 2024.01.12 14:46:42 -05'00'

Thomas W. Prevoznik
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

Jim Walden
John Curran
Walden Macht & Haran
Counsel for Morris & Dickson

Appendix A
May 19, 2023 Order and May 23, 2023 Amended Order
Provided in earlier Submission/Notification

Appendix B
Compliance Addendum
Omitted from Submission as Proprietary and Confidential Information

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Delcath Systems, Inc.

Physical Address: 95 Park Road

City: Queensbury State: NY Zip: 12804

Mailing Address (if different from physical address): 566 Queensbury Avenue

City: Queensbury State: NY Zip: 12804

Telephone: 518-743-8892 Website: www.delcath.com

Name of Designated Representative (DR): Deepa Kunapuram

Licensing Company Email: dkunapuram@delcath.com DR Email: dkunapuram@delcath.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A **Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): N/A - Publicly held on NASDAQ

Corporation Name: Delcath Systems, Inc.

Mailing Address: 566 Queensbury Avenue

City: Queensbury State: NY Zip: 12804

Telephone: 518-743-8892 Email: dkunapuram@delcath.com

Contact Person Name: Deepa Kunapuram

Date of SEC Registration: June 16, 2000 | SEC Registration Number: 0000872912 | Stock Exchange Symbol: DCTH

N/A

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment D	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) See Attachment D	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: N/A http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Delcath Systems, Inc.

Facility Name

Deepa Kunapuram

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

19-Dec-2023

Date

Board Use Only	Date Received: 12/26/23	Amount: $1000 check 0000090206

Attachment A

Nature of Business

Delcath Systems, Inc. "Delcath" is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Delcath plans to market a combination product, HEPZATO™ Kit (melphalan hydrochloride for Injection/Hepatic Delivery System or Melphalan/HDS) for the treatment of patients with unresectable hepatic-dominant metastatic ocular melanoma (mOM). Delcath's Queensbury Avenue location will manufacture the device component. A contract manufacturer will be used to produce the drug product component. The final kit will be assembled by Delcath's Park Road location.

Device Manufacturing Location:

Delcath Systems, Inc.
566 Queensbury Avenue
Queensbury, NY 12804

Sales, Kit Assembly & Distribution Location:

Delcath Systems, Inc.
95 Park Road
Queensbury, NY 12804

Contract Drug Manufacturing Location:

NerPharMa S.r.l
Viale Pasteur 10 – CP11 20014
Nerviano, Milano Italy
FDA Registration #: 3004762406

Attachment B

FDA Registration

The FDA Establishment Registration number provided is for devices. The facility will obtain its drug Establishment Registration shortly. Once available, proof of FDA drug Establishment Registration will be provided upon request. Enclosed is proof of Delcath Systems, Inc.'s FDA labeler code registration number.

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Delcath Systems Inc
566 Queensbury Ave
Queensbury, NY 12804
Registration Number: 3008822486
FEI Number*: 3008822486
Status: Active
Date Of Registration Status: 2023

Owner/Operator:
Delcath Systems, Inc.[6]
Delcath Systems
566 Queensbury Avenue
Queensbury, NY, US 12804
Owner/Operator Number: 100364547

Official Correspondent:
Scott Kiggins
Delcath Systems
566 Queensbury Avenue
Queensbury, NY 12804
Phone: 518-7438892-357

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set.

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=100364547&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establish

Page Last Updated: 02/13/2023

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=100364547&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establish
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=100364547&OwnerOperatorName=&ProductCode=&DeviceName=&ProprietaryName=&establish

NDC/NHRIC Labeler Code	Firm Name
73373	Edith and Nancy LLC
73741	Cemi International, Inc
45865	Medsource Pharmaceuticals
73675	ST Pharm Co., Ltd.
80496	Boreslow Chemical Company
69092	Matrix Source USA, Inc.
53852	Living Well Remedies, LLC
73802	Commonwealth Homes, Inc.
76299	MIST PHARMACEUTICALS, LLC
58913	LOS ALAMOS NATIONAL SECURITY, LLC
44363	ICP Care Pharmacy
67877	Ascend Laboratories, LLC
70873	Simply Clean LLC
67355	NuWest Milling, LLC
75045	Disruption Grain LLC
41315	Jinhua Jinshangtianhua Toy Co., Ltd.
65217	Frances Mahon Deaconess Hospital Home Oxygen
81264	Labotek Group Corp
73275	Vallsura, LLC
78080	MaKMac Inc.
81155	Elemental Bliss LLC
69808	AFFINITY GROUP L.L.C.
58962	NeoMPS, Inc.
66831	Arroyo Medical Supply dba Zia Health Care
53873	Bora Pharmaceutical Services Inc.
76484	Advanced Dental Anesthetics, LLC
0096	Person and Covey
80017	Broder Bros Prime Line
65637	Generitech Corporation
69197	Command Brands, LLC
78133	HAMILTON DISTILLERS GROUP, INC.
59088	PureTek Corporation
78581	TJZ Sanitizer Products LLC
77833	Salmon River Manufacturing Inc.
50562	Alliance Welding Supplies Inc dba Atlas Welding Supply
78032	Doc Disinfectant LLC
52935	YUNG ZIP CHEMICAL INDUSTRIAL CO., LTD.
62242	EBAIN Corporation Co., Ltd.
68776	Alex C. Fergusson, Inc.
73733	N2N Global, LLC
61095	GT Industries Inc.
64942	Conopco Inc. d/b/a Unilever
45562	Lundbeck Pharmaceuticals Italy SpA
75899	Malladi Specialities Limited
78440	INTERNATIONAL GENERAL TRADING CORP
71667	Glamcos L.L.C.
73750	GYK BRANDS LLC
78173	Beltway Brewing Company LLC
70329	STL International INC.
69565	Mannel USA LLC
75833	**Delcath Systems, Inc.**
72833	ASP Cares
62227	BrightGene Bio-Medical Technology Co., Ltd.
75533	MIO-GUARD LLC
48462	DUY DRUGS, INC
71511	Athena Bioscience, LLC
0694	Wyeth Pharmaceuticals Company
63419	Eli Lilly Kinsale Limited
73821	Blinking Owl Distillery
62377	EWS Welding Supply Inc
0472	Actavis Pharma, Inc.
81696	Premalux, LLC
49812	Johnson Matthey Inc.
51770	OLE HENRIKSEN
59800	Schwabe North America, Inc.
74615	B. T. O. Distillers, LLC
42791	H.Q. Specialty Pharma Corporation
74233	Human Biosciences
42488	Dalian Wista Pharma Co., Ltd.
62337	Neogen Corporation dba Columbia Laboratories
27190	Patient Aids, Inc. dba Home Respiratory Service
74783	Georgia Pallet Design, LLC
54948	MIX & MATCH CO., LTD.
62559	Mid Valley Pharmaceuticals LLC
75753	Brazilian Hair LLC
62936	Ingles Markets
68276	Aaxis Pharmaceuticals Inc. dba Aaxis Pacific
14171	Grassroots Life
41524	Ambiopharm, Inc.
61939	Mikah Pharma, LLC
76462	AbbVie Biotechnology LTD
76403	BSV Bioscience GmbH
67007	Grayson O. Company
60881	Allen Medical, Inc.
58247	Respitek Inc.
69844	Gravit Pharmaceuticals Private Limited
77323	Bardenay Inc.
81178	NUTRASTATE, LLC
72840	Kangaroo Oral Care, LLC
77643	Rabusta Coffee and Trading LLC
75220	117 West Spirits
25251	OxyAir Medical LLC
60980	Indian River Oxygen, Inc.
57699	A & G Pharmaceuticals, Inc.
74284	Reclaim Pharmaceutical Waste Management
68429	GHC Group, LLC
75688	MediUSA Inc.
78979	Mgr Design International Inc.
46708	Alembic Pharmaceuticals Limited
77234	Henwil Corporation
69749	Vasseur International Inc.
62588	Earth Baby, Inc.
74858	UI Global Brands LLC
75947	Dicalabria Inc.
48886	Xinxiang Tuoxin Biochemical Technology and Science Co., Ltd.
80771	Wild Horse 777, Inc.
66406	Patheon Inc.
81246	Allakos Inc.
74358	Nittany Valley Distilling, LLC
58964	Sinhwa Life Health Co Ltd
58649	HANGZHOU MINSHENG PHARMACEUTICAL CO., LTD.
77433	Broadslab Distillery LLC
65643	Lifetech Resources, LLC
50760	Corpsain SA de CV
74226	Homeland Energy Solutions LLC
76475	Quo Vademus LLC
73595	Alexandria Professional, LLC

Verified labeler
M.H 1/4/24

Delcath's labeler code 75833 was sought and obtained by our consultants at Beckloff Associates in November 2010. At that time, Beckloff was our e-publishing service provider and they obtained the labeler code via FDA's electronic portal. Please see **NDC/NHRIC Labeler Code 69565 Mannel USA LLC (row 15388)** of the attached FDA Labeler Code database for declaration of Delcath Systems, Inc., which we confirmed last year, when preparing Hepzato labeling for the NDA resubmission.

NDC/NHRIC Labeler Code	Firm Name
69890	HEALINGAM CO., LTD.
69383	Vital Laboratories Private Ltd.
72640	MSN Life Sciences Private Limited.
74149	Yiwu Yangjia Daily Chemicals Co.,Ltd.
61358	LUNG CHOY SHUNG FIVE PHOTOS BRAND MEDICINE FTY.
54369	Total Body Care Inc.
76851	Grace & Stella Inc.
61885	Orean Personal Care Ltd.
69694	Nature In
69922	Groupe Marcelle Inc.
69946	BNK CO., LTD.
70808	Phytoplenus Bioativos SA
69655	LEO Laboratories Ltd.
69728	PROSANA DISTRIBUCIONES, S.A. DE C.V.
76390	Shanghai Soap Co., Ltd.
53604	Atabay Kimya Sanayi ve Ticaret Anonim Sirketi
79487	Liz Corporation Ltd.
71216	Zhejiang Pure Pharmaceutical Co., Ltd.
73735	PASCAL INTERNATIONAL
70961	Acosmetic Co.ltd
12698	Bristol Myers Squibb Srl
72397	VIVAKOREA
71786	Codecosme International Co., Ltd.
69723	MOLCLONE LABS PRIVATE LIMITED.
48943	Chongqing Huapont Shengchem Pharmaceutical Co., Ltd.
69628	Maywell Co., Ltd.
78607	ORGANIKA KIMYA KOZMETIK VE AMBALAJ SANAYI TICARET
70784	NSB CO., LTD.
66529	Jiangsu Hansoh Pharmaceutical Group Co., Ltd.
69451	Nuvo Research Inc.
71322	Sonatural Global Co.,Ltd.
69629	SKIN M.D. KOREA
67623	BIOCOSMETICA EXEL ARGENTINA S.R.L.
69617	Apex Healthcare Limited
69739	1004LABORATORY
76114	Zhejiang Aidi Cosmetics Co., Ltd.
78916	Creme de la Cream Company B.V.
71870	Winner Medical (Jiayu) Co., Ltd.
70652	Roothouse
12070	DCS Pharma AG
63388	Laboratoire Atlas Inc.
70812	BIO STECH CO., LTD.
56153	Ming Fai Industrial (Shenzhen) Co. Ltd.
42283	AC Marca Personal Care
78023	U2
71310	Taizhou Kangping Medical Science And Technology Co., Ltd.
70987	BEAUTIST CO., LTD.
70079	Pure Hold Ltd.
71121	DOCTORCOS CO., LTD.
70759	Pharmaniuco
72802	BETHESKIN Co. Ltd.
70540	INNOGENE CO., LTD.
50555	KMPHARMACEUTICAL CO.,LTD.
71618	Compex Cosmetic GmbH & Co.KG
80830	Puniska Healthcare Private Limited.
70629	KusuMa PharMa
81398	Charmwhite Co.,ltd
71759	Yj Lab Co., Ltd.
73172	Vitabath Inc.
70766	Yangzhou SION Commodity Co.,Ltd.
71857	BSG H & B Co.Ltd.
70541	Dongkook Pharmaceutical Co., Ltd.
42128	Agno Pharma Jiangsu
70815	INDO ABADI SARI MAKMUR, PT.
76396	Aenova France
70799	Alfasigma S.p.A.
72173	JBKLAB Co., Ltd.
72169	Youngwon Costech Co.,ltd.
73288	NINGBO TIANBO FIRST AID PRODUCT CO., LTD.
72582	Contrad Swiss SA
70831	INNER MONGOLIA HUASHU BIOLOGICAL TECHNOLOGY CO.,LTD.
71774	FINEPLUS Co.,Ltd.
49657	Alcon Biosciences Private Limited.
71039	Cell Activation Research Institute Co., Ltd.
72135	Luoding Quality Amenities Supply Limited.
66558	Fresenius Kabi iPSUM S.r.l.
69879	Luxe Art Beaute SAS.
72431	Grupo Pogami SA de CV.
72742	Zen Chemicals Private Limited.
70602	LIFEON Corp.
71447	LABORATOIRES DRUIDE INC.
71637	Verma Industrie-verpackung GmbH & Co. Kg. Kontrakt - Abfüllung Und -verpackung
75368	U&D2 Co.,Ltd.
72211	Picobio Co., Ltd.
71417	Jindal Drugs Private Limited.
67520	Sol-Gel Technologies Ltd.
75765	Samhyun pharma
72571	ARI BIOTECHNOLOGY CO., LTD.
46163	Fresenius Medical Care de Mexico, S.A. de C.V.
6889	Linde Eckstein GmbH + Co. KG
11517	Kindeva Drug Delivery Limited.
72264	Biolab International Incorporated.
74713	GL Pharm Co.,Ltd.
74710	THE GUNG CO.,LTD.
72798	Nature Factory Co., Ltd.
72255	Oneface co., Ltd.
78098	GUANGZHOU NODA PHARMACEUTICAL TECHNOLOGY INCORPORATED CO., LTD.
72030	ANHUI DONGSHENGYOUBANG PHARMACEUTICAL CO., LTD.
69415	Keen Flow International Limited
79296	HANDY LABS
73398	Suhan Aerosol
71734	JIANGMEN SHUIZIRUN SANITARY ARTICLES CO., LTD.
74085	BIOCHEM KOREA CO.,LTD.
70366	JETPHARMA SA
78370	Guangzhou Xin Qi Cosmetics Co., Ltd.
78814	FARMIRAL, S.A. DE C.V.
78416	Hangzhou Wellbeing Technology Co., Ltd.
81477	SHENZHEN HYDROXY TECHNOLOGY CO.,LTD.
78908	Huizhou Runzhiya Industry Co., Ltd.
69653	Jewoo Medical Co., Ltd.
74770	Shenzhen Lanfan Network Technology Co., Ltd.
75675	GUANGZHOU CANYON BIOTECHNOLOGY CO.,LTD.
70019	ZZIP AG

David Day

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Thursday, July 1, 2021 10:32 AM
To: David Day; CDRH Registration and Listing
Cc: Regulatory Affairs
Subject: RE: RE: [EXTERNAL] Delcath Systems - Facility Registration - REG# 3008822486 / OO# 10036454

Dear David,

I heard back from my supervisor and he advised that this would fall under one registration. The main address would be identified on the registration and then you can add any additional device listings to that registration if necessary. (Only one address can be identified on the registration).

Thank You,

Amanda Livingston
Quality Assurance Specialist

Imports and Registration and Listing Team
Division of Regulatory Programs 2 | Office of Regulatory Programs
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak Bldg 66 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-7400
Reglist@cdrh.fda.gov

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https://www.research.net/s/cdrhcustomerservice?ID=1221&S=E

From: David Day <dday@delcath.com>
Sent: Tuesday, June 29, 2021 12:53 PM
To: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Cc: Regulatory Affairs <regaffairs@delcath.com>
Subject: RE: [EXTERNAL] Delcath Systems - Facility Registration - REG# 3008822486 / OO# 10036454

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Dear Amanda,

Our current registered manufacturing facility -

Delcath Systems
566 Queensbury Ave,
Queensbury
12804
New York

Addition warehouse/manufacturing facility -
Delcath Systems
95/97 Park Road,
Queensbury
12804
New York

Distance apart is 0.7 miles, we own the yellow area, but the two lots are divided by a wood area which we will eventually clear.

Both locations are under the same ownership, both are Delcath Systems.

Both locations are under the same management structure and the same quality management system is deployed in both area.

Thanks

David

David Day
Senior Director, Quality
Delcath Systems Inc
566 Queensbury Avenue
Queensbury, NY 12804
O: 518-743-8892 x 341
M: 518-321-4964

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Tuesday, June 29, 2021 11:43 AM
To: David Day <dday@delcath.com>; CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Cc: Regulatory Affairs <regaffairs@delcath.com>
Subject: RE: [EXTERNAL] Delcath Systems - Facility Registration - REG# 3008822486 / OO# 10036454

Dear David,

Please provide the following information:

- What are the two addresses of the establishments?
- How far apart are they in miles/kilometers?
- Are they under the same ownership?
- Are they under the same management structure and quality systems?

Thank You,

Amanda Livingston
Quality Assurance Specialist

Imports and Registration and Listing Team
Division of Regulatory Programs 2 | Office of Regulatory Programs
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak Bldg 66 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-7400
Reglist@cdrh.fda.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

https://www.research.net/s/cdrhcustomerservice?ID=1221&S=E

From: David Day <dday@delcath.com>
Sent: Tuesday, June 29, 2021 11:30 AM
To: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Cc: Regulatory Affairs <regaffairs@delcath.com>
Subject: [EXTERNAL] Delcath Systems - Facility Registration - REG# 3008822486 / OO# 10036454

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi,

My name is David Day and I am the Senior Director of Quality with Delcath Systems. We are a medical device company that manufacture medical device kits for Export only.

Our Owner/Operator Registration is 10036454 and our Facility Registration FEI Number is 3008822486. I have attached our annual registration.

I want to add an additional warehouse/manufacturing building to our registration. This building is located behind our building but the address is a different road. How do I add this facility to our registration?

Thanks

David

David Day
Senior Director, Quality
Delcath Systems Inc
566 Queensbury Avenue
Queensbury, NY 12804
O: 518-743-8892 x 341
M: 518-321-4964

DELCATH CONFIDENTIALITY NOTICE: This communication is intended solely for the use of the individual to whom it is addressed and may contain information that is privileged, confidential, or otherwise exempt from disclosure under applicable law. If the reader of this communication is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication may be a violation of applicable law and is strictly prohibited. If you have received this communication in error, please notify the sender immediately by replying to this message.

Attachment C

Corporate Officer and Director Information

Delcath Systems, Inc.

Corporate Officers:

Gerard Michel
Chief Executive Officer

John Purpura
Chief Operating Officer

David Hoffman
General Counsel, Chief Compliance Officer, Corporate Secretary

Sandra Pennell
SVP, Finance

Vojislav Vukovic
CMO, Medical Affairs

Kevin Muir
VP, Commercial Operations

Board of Directors:

Dr. Roger G. Stoll, Ph.D.
John Sylvester
Elizabeth Czerepak
Steven Salamon
Gil Aharon
Gerard Michael

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DELCATH SYSTEMS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DELCATH SYSTEMS, INC." WAS INCORPORATED ON THE FIFTH DAY OF AUGUST, A.D. 1988.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2168713 8300

SR# 20233888575

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204519768

Date: 11-03-23

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2023-26

NAME OF SUPERVISOR
DEEPA KUNAPURAM

THIS IS TO CERTIFY

DELCATH SYSTEMS, INC.
95 PARK ROAD
QUEENSBURY, NY 12804

is duly recorded as a

REGISTERED WHOLESALER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF MARCH, 2023.
THIS CERTIFICATE EXPIRES ON THE TWENTY-EIGHTH DAY OF FEBRUARY, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
032535

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
11/30/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
AHT Insurance
600 University St #1200
Seattle WA 98101

CONTACT NAME: Curtis Hulme
PHONE (A/C, No, Ext): 206-269-0122
FAX (A/C, No): 703-771-1852
E-MAIL ADDRESS: Curtis.Hulme@ahtins.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Travelers Property Casualty Co	25674
INSURER B : Charter Oak Fire Insurance Com	25615
INSURER C : Gemini Insurance Company	10833
INSURER D : Houston Casualty Co	42374
INSURER E : Federal Insurance Company	20281
INSURER F :	

INSURED
Delcath Systems, Inc.
1633 Broadway, Suite 22C
New York NY 10019
DELCSYS-01

COVERAGES **CERTIFICATE NUMBER:** 38325849 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY			ZLP 31N46672	11/30/2023	11/30/2024	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 0
	OTHER:							$
A	AUTOMOBILE LIABILITY			BA 0K475198	11/30/2023	11/30/2024	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			CUP-3L340312	11/30/2023	11/30/2024	EACH OCCURRENCE	$ 9,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 9,000,000
	DED X RETENTION $ 10,000							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			UB 8S114106	11/30/2023	11/30/2024	X PER STATUTE OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)		N / A				E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Products Liability			GL-11300-12	11/30/2023	11/30/2024	Each Occur/Aggregate	$10000000
D	Cyber Liability			H23NGP232249-00	11/30/2023	11/30/2024	Per Claim/Aggregate	$3000000
E	Crime			J06475437	11/30/2023	11/30/2024	Limit	$1000000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Liability Insurance

CERTIFICATE HOLDER

Evidence of Liability Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Delcath Systems, Inc. MDEG License # (if applicable): N/A

Physical Address: 95 Park Road

City: Queensbury State: NY Zip: 12804

Mailing Address (if different from physical address): 566 Queensbury Avenue

City: Queensbury State: NY Zip: 12804

Telephone: 518-743-8892 Ext: 334 Website: www.delcath.com

Licensing Company Email: dkunapuram@delcath.com

Section 2: Personal Information

First: Deepa Middle: N/A Last: Kunapuram

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Queensbury State: NY Zip: 12804

Telephone: 518-743-8892 Ext: 334 Email: dkunapuram@delcath.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of Memphis		09/2003	- 12/2011
Address	**City**	**State**	**Zip**
3720 Alumni Ave.	Memphis	TN	
Diploma/Degree obtained, if any			
PhD (Analytical Chemistry)			
School Name		**From - To (MM/YY – MM/YY)**	
The University of Memphis		09/2003	- 5/2007
Address	**City**	**State**	**Zip**
3720 Alumni Ave.	Memphis	TN	
Diploma/Degree obtained, if any			
Master of Sciences (Analytical Chemistry)			
School Name		**From - To (MM/YY – MM/YY)**	
Osmania University		09/1999	- 9/2002
Address	**City**	**State**	**Zip**
Administrative Building, Osmania University Campus	Hyderabad, India		
Diploma/Degree obtained, if any			
Bachelor of Pharmacy (B.S. Pharmacy)			
School Name		**From - To (MM/YY – MM/YY)**	
Ramakrishna Jr. College		6/1995 - 5/1996	
Address	**City**	**State**	**Zip**
A.S.Rao Nagar	Hyderabad, India		
Diploma/Degree obtained, if any			
11th and 12th grades			
School Name		**From - To (MM/YY – MM/YY**	
Madonna Public School		6/1996 - 5/1998	
Address	**City**	**State**	**Zip**
42-23/7, Opposite Kushaiguda Bus Stop, Moula Ali	Hyderabad, India		
Diploma/Degree obtained, if any			
10th grade			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2020 - present	[redacted]	Ballston Spa	NY	12020
8/2018 - 11/2020		Saratoga Springs	NY	12866
7/2018 - 8/2018		Saratoga Springs	NY	12866
6/2017 - 7/2018		Prospect	KY	40059
11/2013 - 6/2017		Collierville	TN	38017
01/2010- 11/2013		Cordova	TN	38108
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Delcath Systems, Inc.			6/2020 - present	
Business Address		**City**	**State**	**Zip**
95 Park Road		Queensbury	NY	12804
Phone	**Title**		**Number of Employed Hours**	
518-743-8892	Analytical Chemist		~4,000 hours	

Description of Duties

Develop and perform in-vitro testing in house, collect samples, and prepare samples for laboratory analytical testing. Work with external vendors and scientists to organize research. Writing testing protocols including tests and experiments, authoring reports, as required. Deliver technical data to the team. Operate laboratory under GMP compliance.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Deepa Kunapuram **, certify that as the MDEG Administrator for**

Delcath Systems, Inc.,

that I (initial that you have read and meet the following requirements):

1. DK Have a high school diploma or its equivalent;
2. DK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. DK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. DK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Deepa Kunapuram
Print Name (First, Last)

Deepa
Original Signature (electronic, copies or stamps not accepted)

19-Dec-2023
Date

Board Use Only	Date Received: 12/7/2023

Attachment F

List of Employees

1. Deepa Kunapuram (Analytical Chemist)
2. Jessica Hogan (Laboratory Technician)
3. Roland Schenk (Operations Manager)
4. Daniel Newell (Machine Operator)
5. Stephen Ingram (Machine Operator)
6. Mark Rock (Material Handler)

Attachment D

SEC Report and Top Shareholders

1. Logos Global Management LP 11.10%
2. BVF Partners LP 11.10%
3. Rosalind Advisors, Inc. 8.84%
4. Soleus Capital Management LP (Inv..) 7.59%

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the fiscal year ended December 31, 2022

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the transition period from _____ to _____

Commission file number: 001-16133

DELCATH SYSTEMS, INC.

Delaware	**06-1245881**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1633 Broadway, Suite 22C New York, NY	**10019**
(Address of principal executive offices)	**(Zip Code)**

212-489-2100

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value per share	**DCTH**	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Auditor PCAOB ID Number: 688 Auditor Name: Marcum LLP Auditor Location: New York, NY

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing sale price on the Nasdaq Capital Market of $3.99 per share, as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter was $31,947,845.

At March 24, 2023, the registrant had outstanding 10,061,988 shares of common stock, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2023 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022.

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Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K for the period ended December 31, 2022 contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 with respect to our business, financial condition, liquidity, and results of operations. Words such as "anticipates," "expects," "intends," "plans," "predicts," "believes," "seeks," "estimates," "could," "would," "will," "may," "can," "continue," "potential," "should," and the negative of these terms or other comparable terminology often identify forward-looking statements. Statements in this Annual Report on Form 10-K for the period ending December 31, 2022 that are not historical facts are hereby identified as "forward-looking statements" for the purpose of the safe harbor provided by Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. These forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements, including the risks discussed in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 in Item 1A under "Risk Factors" and the risks detailed from time to time in our future SEC reports. These forward-looking statements include, but are not limited to, statements about:

- our estimates regarding sufficiency of our cash resources, anticipated capital requirements and our need for additional financing;
- actions by the FDA relating to the Company's New Drug Application resubmission;
- the ability of the Company to respond to FDA queries related to the New Drug Application resubmission;
- the Company's successful inspections by the FDA or foreign regulatory agencies;
- the commencement of future clinical trials and the results and timing of those clinical trials;
- our ability to successfully commercialize CHEMOSAT and HEPZATO, generate revenue and successfully obtain reimbursement for the procedure and system;
- the progress and results of our research and development programs;
- submission and timing of applications for regulatory approval and approval thereof;
- our ability to successfully source certain components of CHEMOSAT and HEPZATO and enter into supplier contracts;
- our ability to successfully manufacture CHEMOSAT and HEPZATO;
- our ability to successfully negotiate and enter into agreements with distribution, strategic and corporate partners, and
- our estimates of potential market opportunities and our ability to successfully realize these opportunities.

Many of the important factors that will determine these results are beyond our ability to control or predict. You are cautioned not to put undue reliance on any forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. Except as otherwise required by law, we do not assume any obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

This Annual Report on Form 10-K and the information incorporated herein by reference may include trademarks, service marks and trade names owned or licensed by us, including CHEMOFUSE, CHEMOSAT, CHEMOSATURATION, DELCATH, HEPZATO, HEPZATO KIT, PHP and THE DELCATH PHP SYSTEM. Solely for convenience and readability, trademarks, service marks and trade names, including logos, artwork and other visual displays, may appear in a non-traditional trademark usage manner, including without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent

under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. All trademarks, service marks and trade names included or incorporated by reference into this Annual Report on Form 10-K are the property of the Company or the Company's licensor, as applicable.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. We will be unable to continue to operate for the foreseeable future without additional capital.
- We will need additional capital to maintain our operations. If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, complete our clinical trials or conduct future product development and clinical trials.
- Drug development is an inherently uncertain process with a high risk of failure at every stage of development. On February 12, 2013, we received a complete response letter from the FDA declining to approve our New Drug Application, or NDA, in its then current form. We resubmitted a New Drug Application with the FDA on February 14, 2023; however, there is no guarantee that the FDA will accept our resubmitted NDA, or ultimately approve it.
- The Company does not expect to generate significant revenue for the foreseeable future.
- Continuing losses may exhaust our capital resources.
- If we cannot raise additional capital, our potential to generate future revenues will be significantly limited since we may not be able to further commercialize CHEMOSAT and HEPZATO, or conduct future product development and clinical trials.
- Our failure to obtain, or delays in obtaining, regulatory approvals may have a material adverse effect on our business, financial condition and results of operations.
- We have obtained the right to affix the CE Mark for the CHEMOSAT Hepatic Delivery System as a medical device for the delivery of melphalan. Since we may only promote the device within this specific indication, if physicians are unwilling to obtain melphalan separately for use with CHEMOSAT, our ability to commercialize CHEMOSAT in the EU will be significantly limited.
- We are subject to significant ongoing regulatory obligations and oversight in the EU and will be subject to such obligations in any other country where we receive marketing authorization or approval.
- The development and approval process in the United States is time consuming, requires substantial resources and may never lead to the approval of HEPZATO by the FDA for use in the United States. The FDA may reject our New Drug Application resubmission or refuse to approve the New Drug Application for HEPZATO.
- If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market HEPZATO for other indications.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.
- We rely on third parties to conduct certain elements of the clinical trials for CHEMOSAT and HEPZATO, and if these third parties do not perform their obligations to us, we may not be able to obtain regulatory approvals for our system.
- Purchasers of CHEMOSAT in the EU may not receive third-party reimbursement or such reimbursement may be inadequate. Without adequate reimbursement, commercialization of CHEMOSAT in the EU may not be successful. The success of any of our products may be harmed if the government, private health insurers or other third-party payers do not provide sufficient coverage or reimbursement.

- CHEMOSAT and HEPZATO may not achieve sufficient acceptance by the medical community to sustain our business.
- We may be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- Compliance with laws and regulations pertaining to the privacy and security of health information may be time consuming, difficult and costly for us, particularly in light of increased focus on privacy issues in countries around the world, including the U.S. and in the EU.
- Changes in health care law and governmental policies and initiatives with respect to health care, including government restrictions on pricing and reimbursement and other health care payor cost-containment initiatives, may have a material adverse effect on us.
- Changes in general market, economic, and political conditions, as well as uncertainty resulting from the COVID-19 pandemic, geopolitical tensions, and other macroeconomic conditions.
- Consolidation in the healthcare industry could lead to demands for price concessions.
- We may not be able to enter into or maintain acceptable arrangements for the supply of components and/or raw materials needed for the manufacture of HEPZATO and/or CHEMOSAT.
- If we cannot maintain or enter into acceptable arrangements for the production of melphalan and other chemotherapeutic agents we will be unable to successfully commercialize HEPZATO in the United States or complete any future clinical trials.
- If we cannot successfully manufacture CHEMOSAT and HEPZATO, our ability to develop and commercialize the system would be impaired.
- Even if we receive FDA or other foreign regulatory approvals, we may be unsuccessful in commercializing our product in markets outside the EU, because of inadequate infrastructure or an ineffective commercialization strategy.
- Any plan by the Company to use collaborative arrangements with third parties to help finance and to market and sell CHEMOSAT and HEPZATO may not be successful.

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Item 1. Business.

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "Delcath", "Delcath Systems", "we", "our", and "us" refers to Delcath Systems, Inc., a Delaware corporation, incorporated in August 1988, and all entities included in our consolidated financial statements. Our corporate offices are located at 1633 Broadway, Suite 22C, New York, New York 10019. Our telephone number is (212) 489-2100 and our internet address is www.delcath.com.

Company Overview

We are an interventional oncology company focused on the treatment of primary and metastatic liver cancers. Our lead product candidate, the HEPZATO® KIT (melphalan hydrochloride for injection/hepatic delivery system), or HEPZATO, is a drug/device combination product designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects. In Europe, the hepatic delivery system is a stand-alone medical device having the same device components as the HEPZATO but without the melphalan hydrochloride and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used at major medical centers to treat a wide range of cancers of the liver. Approximately consisting primarily of metastatic ocular melanoma, or mOM. Approximately 80% of the estimated 800 patients annually with mOM will be eligible for would be candidates for HEPZATO.

In the United States, HEPZATO is considered a combination drug and device product and is regulated as a drug by the United States Food and Drug Administration, or the FDA. Primary jurisdiction for regulation of HEPZATO has been assigned to the FDA's Center for Drug Evaluation and Research. The FDA has granted Delcath six orphan drug designations (five for melphalan the treatment of patients with ocular (uveal) melanoma cutaneous melanoma, intrahepatic cholangiocarcinoma, hepatocellular carcinoma, and neuroendocrine tumor indications and one for doxorubicin in the treatment of patients with hepatocellular carcinoma). HEPZATO has not been approved for sale in the United States.

Our clinical development program for HEPZATO is comprised of the FOCUS Clinical Trial for Patients with Hepatic Dominant Ocular Melanoma (the "FOCUS Trial"), a global registration clinical trial that is investigating objective response rate in metastatic ocular melanoma, or mOM, a type of primary liver cancer. Our most advanced development program is the treatment of mOM. We are currently reviewing the incidence, unmet need, available efficacy data and development requirements for a broad set of liver cancers in order to select a portfolio of follow-on indications that will maximize the value of the HEPZATO platform. In addition to HEPZATO's use to treat mOM, we believe that HEPZATO has the potential to treat other liver dominant cancers, such as Metastatic Colorectal Cancer and Cholangiocarcinoma, and plan to begin the study of HEPZATO to treat such conditions in the near future. We believe that the disease states we are investigating and intend to investigate are unmet medical needs that represent significant market opportunities.

In December 2021, the Company announced that the FOCUS Trial for HEPZATO met its pre-specified endpoint.

On February 14, 2023, the Company completed a NDA resubmission to the FDA for the HEPZATO Kit (melphalan hydrochloride for Injection/Hepatic Delivery System) seeking approval of the HEPZATO Kit in the treatment of patients with unresectable hepatic-dominant mOM. The resubmission is in response to a September 12, 2013 Complete Response Letter, or CRL, from the FDA for the Company's NDA in December 2010 seeking approval of its first generation melphalan hydrochloride for injection/hepatic delivery system. The NDA resubmission contains comprehensive data and information on Generation Two HEPZATO Kit relating to the matters identified in the CRL. On March 20, 2023, the FDA determined the resubmission constituted a complete response and set a Prescription Drug User Fee Act target action date of August 14, 2023. We continue to have early access programs in the United States to make HEPZATO available to mOM patients. We are focused on continuing to treat these patients with mOM as regulatory approval is sought in the United States.

On February 28, 2022, CHEMOSAT received Medical Device Regulation (MDR) certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe.

Cancers in the Liver—A Significant Unmet Need

According to the American Cancer Society's, or ACS, *Cancer Facts & Figures 2023* report, cancer is the second leading cause of death in the United States, with an estimated 609,820 deaths and over 1.9 million new cases expected to be diagnosed in 2023. Cancer is one of the leading causes of death worldwide, accounting for approximately 10 million deaths and 19.3 million new cases in 2020 according to GLOBOCAN, the database of the International Association of Cancer Registries. The financial burden of cancer is enormous for patients, their families and society. The Agency for Healthcare Quality and Research estimates that the direct medical costs (total of all healthcare expenditures) for cancer in the United States in 2018 was $112.5 billion. The liver is often the life-limiting organ for cancer patients and cancer that spreads to the liver is one of the leading causes of cancer death. Cancer that begins in one area of the body often metastasizes to the liver. Patient prognosis is generally poor once cancer has spread to the liver. Consequently, cancers of the liver remain a major unmet medical need globally.

Liver Cancers—Incidence and Mortality

Cancers of the liver consist of primary liver cancer and metastatic liver cancer. Primary liver cancers (hepatocellular carcinoma, or HCC, and Intrahepatic Cholangiocarcinoma or ICC) originates in the liver or biliary tissue and is particularly prevalent in populations where the primary risk factors for the disease, such as hepatitis-B, hepatitis-C, high levels of alcohol consumption, aflatoxin, cigarette smoking and exposure to industrial pollutants, are present. Metastatic liver cancer, also called liver metastasis, or secondary liver cancer, results from the spread or "metastases" of a primary cancer into the liver. These metastases often continue to grow even after the primary cancer in another part of the body has been removed. Given the vital biological functions of the liver, including processing nutrients from food and filtering toxins from the blood, it is not uncommon for metastases to settle in the liver. In many cases patients die not as a result of their primary cancer, but from the tumors that metastasize to their liver. In the United States, metastatic liver disease is more prevalent than primary liver cancer. In Europe and the United States, there are over 200,000 primary and metastatic liver tumors per year. It is estimated the total addressable market in the United States for mOM, ICC, HCC breast cancer, neuroendocrine, pancreatic, and colorectal, is over $1.0 billion.

The liver is a difficult organ to treat for certain cancers. Current liver treatment options include surgery, systemic drugs, and minimally invasive or liver directed options. Surgery options include surgical resections, liver transplants, and isolated hepatic perfusion, or IHP. We believe that IHP results in mOM provided rational for PHP in mOM, as well as other tumor types, including colorectal cancer. Systemic options include systemic chemotherapy, immunotherapy agents including KIMMTRAK. Minimally invasive options include external beam radiation therapy and liver directed procedures. Procedures in the liver, liver directed (interventional oncology) are performed by an interventional radiologist. These procedures include trans-arterial chemoembolization (TACE, DEBTACE) and Radioembolization (SIRT, TARE, or Y90). TACE is performing approximately 50,000 to 60,000 treatments per year and Y90 is performing 10,000 to 15,000 treatment per year. We believe that CHEMOSAT and HEPZATO, if approved in the United States, represent an important advancement in regional therapy for liver directed treatment of primary liver cancer and certain other cancers metastatic to the liver and are uniquely positioned to treat the entire liver either as a standalone therapy or as a complement to other therapies. Patients at our early access programs have included first line of stand alone treatment, first line treatment for those intending to receive KIMMTRAK as second line treatment, and as a third line palliative treatment.

Ocular Melanoma

Ocular melanoma frequently metastasizes to the liver. Based on third party research that we commissioned approximately 5,000-6,200 cases of ocular melanoma are diagnosed in the United States and Europe annually, and approximately 50% of these patients will develop metastatic disease. Of metastatic cases of ocular melanoma, approximately 90% of patients develop liver involvement. According to Lane et al., *JAMA Ophthalmol.* 2018 Sep 1;136(9):981-98, once ocular melanoma has spread to the liver, median overall survival for these patients is up to 12 months. There is no one standard of care for patients with ocular melanoma liver metastases. Based on our research, an estimated 800 patients with ocular melanoma liver metastases in the United States, and 1,200 patients in Europe may be eligible for treatment with HEPZATO annually. Currently 55% of the patients have no approved treatment option and most of those patients are treated with multiple lines of therapy. We estimate the annual addressable market for this indication in the United States and Europe is approximately $500 million per year.

Intrahepatic Cholangiocarcinoma

Primary liver cancers include HCC and ICC. According to GLOBOCAN 2020, an estimated 68,500 new cases of primary liver cancer are diagnosed in the United States and Europe annually. According to the ACS, approximately 41,260 new cases of these cancers are expected to be diagnosed in the United States, leading to approximately 30,520 deaths.

ICC is the second most common form of primary liver cancer and according to Wang et al., 2013 J Clin Oncol 31:1188-1195 accounts for 5-30% of primary liver cancers diagnosed in the United States and Europe annually. We believe that 80% of ICC patients are not candidates for surgical resection, and that approximately 20-30% of these may be candidates for certain focal interventions. According to third party research that we commissioned, we estimate that approximately 11,000 ICC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with HEPZATO and CHEMOSAT.

Colorectal Cancer

Colorectal cancer or CRC is one of the most prevalent cancers in the United States and Europe and has a high metastatic rate to the liver. GLOBOCAN 2020 estimates 288,230 colorectal cancer diagnosis per year in the United States and Europe. According to the American Cancer Society, in the United States approximately 151,030 diagnoses leading to 52,580 deaths.

Recent advances in the treatment of primary colorectal cancer have shown encouraging increases in 5-year survival; however, the presence of metastasis is an indicator for increased mortality probability. Approximately 25% of patients will present with liver metastasis at the time of initial primary disease diagnosis. Clark et al., *J Gastrointest Oncol* 2014;5(5):374-387. We estimate approximately 98,000 CRC patients in the United States, the United Kingdom and the EU annually could be candidates for treatment with HEPZATO and CHEMOSAT.

Breast Cancer

Breast cancer or BC is the most diagnosed cancer in women in the United States and worldwide. The American Cancer Society estimates that 287,850 women will be diagnosed with BC in the United States annually. BC is the second leading cancer-related cause of death for women (behind lung cancer) in the United States. GLOBOCAN 2020 estimates are that there are, annually, 726,259 women diagnosed with breast cancer in the United States, Western Europe and the United Kingdom. Recent advances in primary breast cancer treatments have given patients a high 5-year survival rate. The prognosis for patients with breast cancer liver metastasis, however, remains poor.

Approximately 18% of all women diagnosed with breast cancer will also have distant metastatic disease, in which 5% of these patients will have liver only metastasis. Eventually 50% of all metastatic patients will see

their disease progress to the liver in addition to their initial diagnosed metastatic site and in 20% of these patient's liver progression is the cause of mortality. *Deipolyi AR, et al.J Vasc Inter Radiol. 2018;29(9):1226-1235.* Treatment options for patients with multiple sites of metastatic disease vary. We estimate that approximately 6,000 breast cancer patients with hepatic only involvement in the United States and Western Europe (including the United Kingdom and Italy) could be candidates for treatment with HEPZATO and CHEMOSAT. An additional 10,000 patients could receive benefits from HEPZATO and CHEMOSAT in the palliative setting based on local treatment guidelines.

Neuroendocrine Cancer

Neuroendocrine Tumors or NETs or neuroendocrine neoplasia are a rare group of cancers that originate in neuroendocrine cells. NETs can originate anywhere in the body, the most common sites include the digestive tract, rectum, lungs, pancreas, or appendix. The American Society of Clinical Oncology estimates that there are 12,000 new diagnosis of neuroendocrine tumors each year in the United States, and a total of 21,500 in the United States and Europe.

According to *Pape et al. 2008. Endocrine-Related Cancer. 15(4). 1083-1097* NETs have a metastasis rate of between 60-80% and the majority of these accrue in the liver (85%). We estimate that approximately 12,000 NETs patients in the United States, the United Kingdom and the European Union each year could be candidates for treatment with HEPZATO and CHEMOSAT.

Pancreatic Cancer

Pancreatic adenocarcinoma comes with a poor prognosis for those diagnosed with the disease. The American Cancer Society estimates that pancreatic cancer will affect 62,210 patients annually, with 49,830 annual deaths in the United States. Along with GLOBOCAN estimates for Western Europe, pancreatic cancer effects a total of 132,442 patients annually with 105,638 annual deaths.

Upon diagnosis, nearly 75% of patients will have liver metastasis and 58% of those patients will have liver only metastasis. Metastatic pancreatic cancer proves to be a fast-progressing cancer that, once metastasized, leaves the patient with limited treatment options. *Oweira, et al. World J Gastroenterol. 2017;23(10):1872-1880.* We estimate there are approximately 57,600 United States and Western Europe new pancreatic cancer patients each year with hepatic only involvement. Given the rapid progression of the disease it is unknown at this time the estimated number of candidates for treatment with HEPZATO and CHEMOSAT.

About CHEMOSAT and HEPZATO

Our product candidate, the HEPZATO Kit, is a drug/device combination product designed to administer concentrated regional chemotherapy to the liver while controlling systemic exposure and associated side effects. This "whole organ" therapy is performed by isolating the circulatory system of the liver, infusing the liver with a chemotherapeutic agent, and then filtering the blood prior to returning it to the patient's circulatory system. During the procedure, known as percutaneous hepatic perfusion, PHP®, or PHP therapy, three catheters are placed percutaneously through standard interventional radiology techniques. The catheters temporarily isolate the liver from the body's circulatory system, allow administration of the chemotherapeutic agent melphalan hydrochloride directly to the liver, and collect blood exiting the liver for filtration by our proprietary filters. The filters adsorb chemotherapeutic agent from the blood, before the filtered blood is returned to the patient's circulatory system thereby reducing systemic exposure to the drug and related toxic side effects.

PHP therapy is performed in an interventional radiology suite in approximately two to three hours. Patients remain in an intensive care or step-down unit overnight for observation following the procedure. Treatment with CHEMOSAT and HEPZATO is repeatable, and a new disposable system is used for each treatment. Patients treated in clinical settings are permitted up to six treatments. In commercial treatment settings, patients have received up to eight treatments. If approved, we expect that the HEPZATO Kit will be appropriate for the

approved indication, regardless of HLA-A *02:01 status. In the United States, melphalan hydrochloride for injection will be included as part of the system, if approved. In Europe, the system is sold separately and used in conjunction with melphalan hydrochloride commercially available from a third party. In our clinical trials, melphalan hydrochloride for injection is provided to both European and United States clinical trial sites.

Early development of HEPZATO System—FDA Complete Response Letter

Based on clinical trials conducted using an earlier version of our HEPZATO system, in August 2012, we submitted an NDA under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, seeking FDA approval for use of our HEPZATO system for the percutaneous intra-arterial administration of melphalan hydrochloride for use in the treatment of patients with metastatic melanoma in the liver and, subsequently, amended the NDA to include ocular melanoma metastatic to the liver.

In the Spring of 2013, an Oncologic Drug Advisory Committee, or ODAC panel, convened by the FDA voted 16 to 0, with no abstentions, that the benefits of treatment with the early version of HEPZATO did not outweigh the risks associated with the procedure. A significant portion of the FDA's presentation to the ODAC panel was focused on the FDA's assessment of treatment-related risks, including the analysis of treatment-related deaths that occurred during clinical trials. The FDA also expressed concerns about hypotension, or low blood pressure, during the procedure, length of hospital stay, as well as risks of stroke, heart attack, renal failure, and bone marrow suppression.

In September 2013, the FDA issued a CRL, relating to our NDA. The FDA issues a CRL after the review of an NDA has been completed and questions remain that preclude approval of the NDA in its current form. The deficiencies identified in the CRL included, among other items, the requirement that we conduct an adequate and well-controlled study demonstrating substantial evidence that the effectiveness of the use of this early version HEPZATO system the Company intended to market outweighed its risks. The CRL also required that we address certain clinical, clinical pharmacology, human factors and product quality elements.

In January 2016, we entered into a Special Protocol Assessment agreement, or SPA, with the FDA on the design of a new Phase 3 clinical trial of HEPZATO to treat patients with hepatic dominant ocular melanoma. This SPA represented an agreement with the FDA that a specific Phase 3 trial would adequately address objectives that, if met, would support the submission for regulatory approval of HEPZATO. The SPA's primary endpoint was overall survival, and secondary endpoints included progression-free survival, overall response rate and quality-of-life measures. However, the Company faced significant difficulties, including the fact that the BAC arm was known to have limited efficacy, enrolling patients into the study under the SPA. Therefore, in the summer of 2018, we amended the protocol for the trial to a non-randomized, single-arm study with a different primary endpoint (objective response rate), which terminated the SPA.

Clinical Development Program

The focus of our clinical development program is to generate clinical data for CHEMOSAT and HEPZATO in various disease states to demonstrate efficacy and validate the safety profile of the current version of the product and treatment procedure. We believe that the improvements we have made to CHEMOSAT, HEPZATO and the PHP therapy have addressed the adverse event profile and procedure-related risks that led to the issuance of the CRL. Our clinical development program is also designed to support clinical adoption of and reimbursement for CHEMOSAT in Europe, and to support regulatory filings and reimbursement in various jurisdictions, including the United States.

The FOCUS Trial

The FOCUS Trial evaluated the safety and efficacy of treatment with the HEPZATO Kit for patients with mOM. The primary endpoint of ORR was assessed by an Independent Review Committee per RECIST v1.1. Per protocol, patients were treated every 6 to 8 weeks for a maximum of 6 cycles. Tumor responses were assessed every 12 weeks (+/- 2 weeks) until disease progression.

Delcath powered the single arm trial to demonstrate a clinically meaningful ORR versus checkpoint inhibitors, one of the few mOM treatment categories with a significant amount of peer reviewed publications. Based on this analysis the 95% Confidence Interval for ORR for checkpoint inhibitors was calculated to be 3.6% - 8.3%. The lower bound at the 95% confidence for ORR for HEPZATO Kit needed to exceed 8.3% to demonstrate a clinically meaningful ORR. While this comparator is not an historical control, the FDA did not object to using the meta-analysis of checkpoint inhibitors to provide support for a clinically meaningful ORR.

The FOCUS Trial's intent-to-treat or ITT population was comprised of a total of 102 mOM subjects and the treated population, which the FDA defined as the primary analysis population, was comprised of 91 patients. Of the 91 patients in the treated population, 51 (56.0%) had no prior therapy for liver metastases and 40 (44.0%) had at least one line of prior therapy. An independent Review Committee assessed response status per RECISTv1.1. Treatment with HEPZATO Kit in the treated population resulted in an ORR of 36.3% [95% CI: 26.44, 47.01] including 7.7% of patients with a complete response or CR. The median duration of response was 14.00 months [95% CI: 8.31, 17.74] and the disease control rate or DCR was 73.6% [95% CI: 63.35, 82.31]. The NDA resubmission included updated estimated median overall survival or OS of 20.53 months [95% CI: 16.79, 25.26] and updated estimated OS at 1 year of 0.80 [95% CI: 0.70, 0.87]. Data was cut as of December 2, 2022 and Delcath will continue to follow patients until May 2023 (24 months after the last patient's last treatment). Since the trial started as a randomized trial, supportive analyses comparing against BAC were also conducted.

In the FOCUS Trial safety population (95 patients), 39 patients (41.1%) experienced a treatment-related serious adverse event. The most commonly reported treatment-related serious adverse events were thrombocytopenia, neutropenia and febrile neutropenia which were well-manageable. Five percent of patients experienced treatment-related serious cardiac adverse events, in all cases the events resolved with no ongoing complications. 17 (17.9%) patients withdrew due to an adverse event or a serious adverse event, while 12 (12.6%) received a reduced dose due to an adverse event or serious adverse event. There were no treatment-related deaths in the trial. This is consistent with CHEMOSAT, the HDS device component of the HEPZATO Kit, approved in Europe under a CE mark to deliver melphalan to the liver. The safety data submitted in the NDA is consistent with the CHEMOSAT safety data documented in numerous European single-center and multi-center publications.

CHOPIN Trial

The Leiden University Medical Center completed a Phase 1b trial (CHOPIN trial) on the use of the Delcath CHEMOSAT® Hepatic Delivery System with Melphalan (CHEMOSAT) in combination with the immune checkpoint inhibitors (ICI) ipilimumab and nivolumab to treat patients with metastatic uveal melanoma with liver metastases.

The goal of the CHOPIN trial is to study the safety and potential synergistic effects of systemic ICI therapy ipilimumab plus nivolumab (IPI+NIVO) when combined with Delcath's proprietary liver-targeted percutaneous hepatic perfusion treatment in metastatic uveal melanoma patients. The just released publication presented updated safety and efficacy results from the Phase 1b portion of the trial which were previously presented in June 2022 at the American Society of Clinical Oncology Annual Meeting. The Phase 1b portion of the trial enrolled seven patients each of which were treated with two courses of PHP (melphalan 3mg/kg, max 220 mg per cycle) combined with four courses IPI+NIVO escalating the dosing from 1mg/kg each IPI+NIVO (cohort 1) to IPI 1mg/kg + NIVO 3mg/kg (cohort 2). As previously reported, the Best Overall Response included 1 complete response, 5 partial responses and 1 stable disease accounting for an Objective Response Rate of 85.7% and a Disease Control Rate of 100%. At the cut-off date of November 15, 2022, the median follow-up was 29.1 months (range 8.9 – 30.2), the median PFS was 29.1 months (95% CI 11.9 – 46.3) and the median duration of response was 27.1 months (range 7.4 – 28.5). All patients are still alive and three of four patients who subsequently experienced PD continued with treatment in the form of repeated melphalan PHP (M-PHP) cycles.

The ongoing randomized phase 2 part of the CHOPIN trial comparing M-PHP alone with M-PHP plus IPI/NIVO, which will include another 76 patients (38 per arm), is approximately 50% enrolled and will provide more insight to the efficacy.

The determination of a safe and effective dose was a primary goal of the Phase 1b portion of the CHOPIN trial. Grade 1/2 adverse events were seen in all patients and 71.4% experienced grade 3/4 toxicities. In this phase 1b dose-escalation study combining M-PHP with IPI/NIVO the safe treatment dose was established at IPI 1mg/kg and NIVO 3mg/kg. The authors did observe low-grade immune-related toxicities and PHP-related hematological toxicities in the treated groups. Hematological toxicity is a common adverse event after M-PHP, affecting approximately three-quarters of patients. All 7 patients in the study experienced grade 1/2 anemia. To prevent severe leukopenia/neutropenia, G-CSF was administered within 48 hours after M-PHP in their treatment center. The phase 2 part of the CHOPIN study will provide more information on both hepatic and systemic toxicity associated with the combination therapy.

Market Access and Commercial Clinical Adoption

Europe

Since launching CHEMOSAT in Europe, there has been over 1,343 commercial treatments and CHEMOSAT is currently available in over 23 European cancer centers. Physicians in Europe have used CHEMOSAT to treat patients with a variety of cancers in the liver, primarily ocular melanoma liver metastases, and other tumor types, including cutaneous melanoma, hepatocellular carcinoma, cholangiocarcinoma, and liver metastases from colorectal cancer, breast, pancreatic and neuroendocrine.

For the period of December 2018 through February 2022, medac GmbH was the Company's exclusive distributor for CHEMOSAT in Europe and had the exclusive right to market and sell CHEMOSAT in all member states of the European Union, Norway, Liechtenstein, Switzerland, and the United Kingdom. As of March 1, 2022, we have assumed direct responsibility for sales, marketing and distribution of CHEMOSAT in Europe. UK upgraded the status from "Research" to "Special Status".

European Reimbursement

A critical driver of utilization growth for CHEMOSAT in Europe is the expansion of reimbursement mechanisms for the procedure in our priority markets. In most European countries, the government provides healthcare and controls reimbursement levels. Since the European Union has no jurisdiction over patient reimbursement or pricing matters in its member states, the methodologies for determining reimbursement rates and the actual rates may vary by country. Reimbursement is administered on a regional and national basis. A medical device is typically reimbursed under a Diagnosis Related Groups, or DRG, as part of a procedure. Prior to obtaining permanent DRG reimbursement codes, in certain jurisdictions, we are actively seeking interim reimbursement from existing mechanisms that include specific interim reimbursement schemes, new technology payment programs as well as existing DRG codes. Currently we have an interim level of reimbursement in Germany. The CE Mark has been affixed to the CHEMOSAT in 23 centers in 4 countries.

On February 28, 2022, CHEMOSAT received Medical Device Regulation certification under the European Medical Devices Regulation [2017/745/EU], which may be considered by jurisdictions when evaluating reimbursement.

The release of the clinical study report from the FOCUS Trial will create the opportunity to apply for National Level reimbursement in each European country in regard to metastatic ocular melanoma (mOM). These applications must be made by us on a country-by-country basis, with priority placed on markets where CHEMOSAT is currently used. Currently, CHEMOSAT is approved for reimbursement in Germany. The results from the Focus Trial may also support existing reimbursement mechanisms, such as existing in Germany, allowing more hospital centers to secure funding to utilize CHEMOSAT. This increased level of evidence will ultimately support securing full funding for the treatment under DRG codes.

Reimbursement applications in priority European markets are handled directly by the Company.

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Government Regulation

Our products are subject to extensive and rigorous government regulation by foreign regulatory agencies and the FDA. Foreign regulatory agencies, the FDA and comparable regulatory agencies in state and local jurisdictions impose extensive requirements upon the clinical development, pre-market clearance and approval, manufacturing, labeling, marketing, advertising and promotion, pricing, storage, and distribution of pharmaceutical and medical device products. Failure to comply with applicable foreign regulatory agency or FDA requirements may result in warning letters, fines, civil or criminal penalties, suspensions, delays in clinical development, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

United States Regulatory Environment

In the United States, the FDA regulates drug and device products under the FDCA, and its implementing regulations. HEPZATO is subject to regulation as a combination product, which means it is composed of both a drug product and a device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center within the FDA that will have primary jurisdiction over its pre-market review and regulation based on a determination of its primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of HEPZATO, the primary mode of action is attributable to the drug component of the product, which means that the Center for Drug Evaluation and Research has primary jurisdiction over its pre-market development and review.

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated periodically, but at least annually;
- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's good laboratory practice, or GLP, regulations;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the FDA of an NDA after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced and tested to assess compliance with current good manufacturing practice, or cGMP, regulations; and
- FDA review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The development and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product will be granted on a timely basis, if at all.

The results of preclinical tests (which include laboratory evaluation as well as GLP studies to evaluate toxicity in animals) for a particular product candidate, together with related manufacturing information and analytical data, are submitted as part of an IND to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. IND submissions may not result in FDA authorization to commence a clinical trial. A separate

submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center, and it must monitor the study until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive good clinical practice regulations and regulations for informed consent and privacy of individually identifiable information. Similar requirements to the United States' IND are required in the European Union and other jurisdictions in which we may conduct clinical trials.

Clinical Trials

For purposes of NDA submission and approval, clinical trials are typically conducted in the following sequential phases, which may overlap:

- Phase 1 Clinical Trials. Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, distribution, metabolism, and excretion, typically in healthy humans, but in some cases in patients.
- Phase 2 Clinical Trials. Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, explore the initial efficacy of the product for specific targeted indications and to determine dose range or pharmacodynamics. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 Clinical Trials. These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial centers.
- Phase 4 Clinical Trials. The FDA may approve an NDA for a product candidate but require that the sponsor conduct additional clinical trials to further assess the drug after NDA approval under a post-approval commitment. In addition, a sponsor may decide to conduct additional clinical trials after the FDA has approved an NDA. Post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors of clinical trials may submit proposals for the design, execution, and analysis for their pivotal trials under a Special Protocol Assessment, or SPA. A SPA is an evaluation by the FDA of a protocol with the goal of reaching an agreement that the Phase 3 trial protocol design, clinical endpoints, and statistical analyses are acceptable to support regulatory approval of the drug product candidate with respect to effectiveness for the indication studied. Under a SPA, the FDA agrees to not later alter its position with respect to adequacy of the design, execution or analyses of the clinical trial intended to form the primary basis of an effectiveness claim in an NDA, without the sponsor's agreement, unless the FDA identifies a substantial scientific issue essential to determining the safety or efficacy of the drug after testing begins.

New Drug Applications

The results of drug development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. An NDA must contain extensive chemistry, manufacturing, and control information and be accompanied by a significant user fee, which may be waived in certain circumstances. Once the submission has been accepted for filing, the FDA should review NDAs within ten months of submission or, if the NDA relates to an unmet medical need in a serious or life-threatening indication, six months from submission. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the NDA to an advisory committee for review, evaluation, and recommendation as to whether the NDA should be approved. For new oncology products, the FDA will often solicit an opinion from an Oncology Drug Advisory

Committee, or ODAC, which is a panel of expert authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunologic oncology, biostatistics, and other related professions. The ODAC panel reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of the FDA. However, the FDA is not bound by the recommendation of an advisory committee and may deny approval of an NDA by issuing a CRL, if the applicable regulatory criteria are not satisfied. A CRL may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies, or manufacturing. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant or its collaborators interpret data. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, or REMS, that limits the labeling, distribution, or promotion of a drug product. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing, including Phase 4 clinical trials, and surveillance programs to monitor the safety and efficacy of approved products which have been commercialized. The FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

There are three primary regulatory pathways for a NDA under Section 505 of the FDCA: Section 505 (b)(1), Section 505 (b)(2) and Section 505(j). A Section 505 (b)(1) NDA is used for approval of a new drug (for clinical use) whose active ingredients have not been previously approved. A Section 505 (b)(2) application is used for a new drug that relies on data not developed by the applicant. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. This statutory provision permits the approval of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Act permits the applicant to rely, in part, upon the FDA's findings of safety and effectiveness for previously approved products. A Section 505(j) NDA, also known as an abbreviated NDA, is used for a generic version of a drug that has already been approved.

Orphan Drug Exclusivity

Some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Pursuant to the U.S. Orphan Drug Act, the FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. The orphan designation is granted for a combination of a drug entity and an indication and, therefore, it can be granted for an existing drug with a new (orphan) indication. Applications are made to the FDA's Office of Orphan Products Development and a decision or request for more information is rendered in 60 days. NDAs for designated orphan drugs are exempt from user fees, obtain additional clinical protocol assistance, are eligible for tax credits for up to 50% of research and development costs, and are granted a seven-year period of exclusivity upon approval. The FDA cannot approve the same drug for the same condition during this period of exclusivity, except in certain circumstances where a new product demonstrates superiority to the original treatment. Exclusivity begins on the date that the marketing application is approved by the FDA for the designated orphan drug, and an orphan designation does not limit the use of that drug in other applications outside the approved designation in either a commercial or investigational setting.

We have received five orphan drug designations for melphalan in the following indications:

- the treatment of patients with cutaneous melanoma;
- the treatment of patients with ocular melanoma;
- the treatment of patients with neuroendocrine tumors;
- the treatment of patients with primary liver cancer, or HCC; and
- the treatment of cholangiocarcinoma, which includes ICC.

We have received one orphan drug designation for doxorubicin for the treatment of patients with primary liver cancer, or HCC.

The granting of orphan drug designations does not mean that the FDA has approved a new drug. Companies seeking new drug approval must still pursue the rigorous development and approval process that requires substantial time, effort, and financial resources. Accordingly, although we have received these orphan drug designations, we cannot be certain that any approvals for our product will be granted at all, or on a timely basis.

Other Regulatory Requirements

Products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including recordkeeping, annual product quality review and reporting requirements. Adverse event experience with the product must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events are mandated by the FDA. Drug manufacturers and their subcontractors must register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon drug manufacturers. Following such inspections, the FDA may issue notices on Form 483 and Untitled Letters or Warning Letters that could require the drug manufacturer to modify certain activities. A Form 483 Notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated cGMP or other FDA regulations or guidelines. In addition to Form 483 Notices and Untitled Letters or Warning Letters, failure to comply with the statutory and regulatory requirements can subject a drug manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, injunctive action or possible civil penalties. We cannot be certain that we or our present or future third-party manufacturers or suppliers will be able to comply with the cGMP regulations and other ongoing FDA regulatory requirements.

If Delcath or its present or future third-party manufacturers or suppliers are not able to comply with these requirements, the FDA may require the recall of our product from distribution or may withdraw any potential approvals of an NDA for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, any drug modifications, including changes in indications, labeling, or manufacturing processes or facilities, may require a submission to the FDA for its approval of a new or supplemental NDA, which may require the development of additional data or the conduct of additional preclinical studies and clinical trials. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties.

Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those that have been tested by the drug manufacturer and approved by the FDA. Such off-label uses are common across medical specialties, in particular in oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Coverage and Reimbursement

Our ability to commercialize any products successfully once approved will depend in part on the availability of coverage and reimbursement from third-party payors, such as government health administration authorities, private health insurers and managed care organizations. Even if we obtain coverage for a given product by a

third-party payor, the third-party payor's reimbursement rates may not be adequate to make the product affordable to patients or profitable to us, or the third-party payors may require co-payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, reimbursement by a third-party payor may depend upon a number of factors including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining and maintaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Further, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

In the United States, decisions about reimbursement for new medicines under Medicare are made by CMS, as the administrator for the Medicare program. We anticipate obtaining a J-Code for HEPTAZO, once approved. J-Codes are part of the Healthcare Common Procedure Coding System, or HCPCS, code as maintained by CMS. However, there is no guarantee that these billing codes, once granted, or the payment amounts, if any, associated with such codes will not change in the future. Private third-party payors often use CMS as a model for their coverage and reimbursement decisions, but also have their own methods and approval process apart from CMS's determinations. Even if favorable coverage and reimbursement status is attained for any of our products or product candidates that receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs, such as by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices as a condition of coverage, are using restrictive formularies and preferred drug lists to leverage greater discounts in competitive classes and are challenging the prices charged for medical products. Further, no uniform policy for determining coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Moreover, third-party payors may require patients to obtain prior authorization before certain treatments, such as HEPTAZO, are provided. Therefore, we intend to contract with a third-party hub service to facilitate the pre-authorization process.

U.S. HealthCare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws have been applied to restrict certain business practices in the biopharmaceutical industry in

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) (parent company is publicly traded) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: The J. Molner Company LLC

Physical Address: 101 Hudson St. 21st Floor, Suite 21102

City: Jersey City State: NJ Zip: 07302

Mailing Address (if different from physical address): Same as Above

City: _____ State: _____ Zip: _____

Telephone: 201-582-3400 Website: www.jmolner.com

Name of Designated Representative (DR): Jason Grenfell-Gardner

Licensing Company Email: jason@jmolner.com DR Email: jason@jmolner.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others: clinics and distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

/A **Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year. See Attachment A

Name: Eversana Life Science Services, LLC
Address: 4580 Mendenhall Road City: Memphis State: TN Zip: 38141
Name: Ferndale Laboratories, Inc.
Address: 780 West Eight Mile Road City: Ferndale State: MI Zip: 48200
Name: Bora Pharmaceutical Services, Inc
Address: 7333 Mississaugua City: Ontario State: Canada Zip: L5N 6L4
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): J. Molner AS (a publicly traded company)
Corporation Name: The J. Molner Company LLC
Mailing Address: 101 Hudson St. 21st Floor, Suite 21102
City: Jersey City State: NJ Zip: 07302
Telephone: 201-582-3600 Email: jason@jmolner.com
Contact Person Name: Jason Grenfell-Gardner

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. N/A - the parent company is publicly traded.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** See Attachment A	✓			
• **List of all corporation shareholders and their percent ownership.** N/A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) See Attachment G	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment E	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

The J. Molner Company LLC

Facility Name

Jason Grenfell-Gardner

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

NOV. 16, 2023

Date

Board Use Only	Date Received: 11/20/23	Amount: $4000 - check 1015

Attachment A

Nature of Business

The J. Molner Company LLC "J. Molner" is a virtual prescription drug manufacturer/distributor. A contract manufacturer will be used to produce the product the company will sell and a third party logistics provider will ship. No product will be handled at J. Molner's business office. Provided below is the contact information for the contract manufacturer and third party logistics provider. J. Molner will sell generic prescription drugs for which a sister company holds FDA approval. Provided below are the products the company intends to sell.

Contract Manufacturer:

Ferndale Laboratories, Inc.
780 West Eight Mile Road
Ferndale, MI 48200
FDA Registration #: 1811212

Third Party Logistics Provider:

EVERSANA Life Science Services, LLC
4580 Mendenhall Road
Memphis, TN 38141

Product:

Diflorasone Diacetate Ointment USP, 0.05%
Hydrocortisone Butyrate Lotion, 0.1%
Desoximetasone Ointment USP, 0.05%

Attachment B

FDA Registration

Subject:

FW: The J. Molner Company LLC - Documentation of FDA Registration

direct.fda.gov/apex/f?p=100:69:103041043949222::NO::P69_HEADER_ID:558302

The J. Molner Company LLC
NDC/NHRIC LABELER CODE REQUEST

Labeler - The J. Molner Company LLC (119066049) **NDC Labeler Code:** 83148	
Contact	**Address**
Jason Grenfell-Gardner	Address: 101 Hudson Street, FL 21 City, State, Zip: Jersey City, NJ, 07302 Country: USA

Labeler Detail	
Name	**Address**
The J. Molner Company LLC	Address: 101 Hudson Street, FL 21 City, State, Zip: Jersey City, NJ, 07302 Country: USA

Revised: 9/2023

Attachment C

LLC Officer Information

The J. Molner Company LLC
101 Hudson St., 21st Floor, Suite 21102
Jersey City, NJ 07302

Jason Grenfell-Gardner
Founder
Business: 201-582-3600
Business address: 101 Hudson St., 21st Floor, Suite 21102, Jersey City, NJ 07302
The J. Molner Company LLC Ownership: 0%

Attachment D

Certificate of Good Standing

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "THE J. MOLNER COMPANY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTH DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "THE J. MOLNER COMPANY LLC" WAS FORMED ON THE NINTH DAY OF AUGUST, A.D. 2021.

Jeffrey W. Bullock, Secretary of State

6153067 8300

SR# 20233923365

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204554540

Date: 11-08-23

Attachment F

Resident State License

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0749633

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

101 HUDSON ST, FL 21, STE 21102 JERSEY CITY, NJ 07302-

Reg. No.
5006353

THE J. MOLNER COMPANY LLC
101 HUDSON ST, FL 21, STE 21102
JERSEY CITY, NJ 07302-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2024

Establishment Copy

Attachment E

List of Employees

Jason Grenfell-Gardner
Founder
Business: 201-582-3600

Attachment G

Public Holding Documentation

The J. Molner Company LLC is wholly-owned by J. Molner AS. J. Molner AS is publicly traded on the NASDAQ First North Baltic Share list. Enclosed please find the first 15 pages of the latest trading filing for the parent company. The entire filing may be viewed online here:

https://nasdaqbaltic.com/statistics/en/instrument/EE3100109034/reports?date=2023-05-31

American stock exchange

CONSOLIDATED INTERIM REPORT FOR THE FIRST 6 MONTHS OF 2023

(UNAUDITED)

beginning of reporting period: 01.01.2023
end of the reporting period: 30.06.2023

business name: J.Molner AS

register code: 16579077

street, building, apartment, farm: Akadeemia tee 21/5
city: Tallinn
county: Harju maakond
postal code: 12618

e-mail address: jmolner@jmolner.com

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Management Report

The Management Report has been prepared for the consolidated financial results of J.Molner AS, The J.Molner Company OÜ and The J.Molner Company LLC (hereinafter the"Group") for the first half year of 2023. J.Molner AS was established on 22.09.2022 as a holding company without independent economical activity. The purpose of establishing J.Molner AS was to enable the initial public offering (IPO) and admission to trading on the First North multilateral trading system of the shareholding in The J. Molner Company OÜ. As the corporate form (private limited company) of The J.Molner Company OÜ, does not allow it to make a public offering of the holding and apply for admission to trading, J.Molner AS as a public limited company was founded. J.Molner AS was established with non-monetary contribution the object of which was a 100% holding in The J. Molner Company OÜ, thus J.Molner AS is the parent company of The J. Molner Company OÜ. The J. Molner Company Inc. is a subsidiary of The J. Molner Company OÜ. In the beginning of 2023, the U.S. entity The J. Molner Company LLC was acquired. The main purpose of the U.S. entity is the sale of the Group's products in the U.S. market.

In January 2023, the Group successfully passed its inspection of Eesti Ravimiamet. During the first half of 2023, the Group continued the development of its own generic drugs and the provision of analytical chemistry and method development services to third parties. In terms of analytical and development services, the Group served customers from the United States, Canada and Europe. In June 2023, the Group submitted its first fully owned drug application to the U.S. Food and Drug Administration. In addition, the Group continued to return to the market three U.S. registered drugs owned by the Group since 2022. The first drug is planned to be returned to the market in the second half of 2023, subject to regulatory approval.

For one drug product, the Group received its first ever new market approval from Health Canada in June 2023; the application for approval for the second drug product was submitted in March, 2023. In April 2023, The Group entered into a licensing agreement with a Canadian pharmaceutical distributor to commercialize two injectable drug products in Canada, pending approval from Health Canada. In addition, the Group has entered into a licensing agreement with the same Canadian pharmaceutical distributor to develop two drug products at the Group's laboratory in Tallinn.

Important notes:

- The Group's business is not seasonal.
- The Group's activities are not accompanied by significant environmental and social impacts.
- Interest rates did not change significantly during the financial year and the period of preparation of the annual report.
- As J.Molner AS was founded using the 100% shareholding in The J.Molner Company OÜ as non-monetary contribution the consolidated comparative data is provided for period 01.10.2022-31.12.2022.

As per 30.06.2023 the total consolidated unaudited balance sheet of J.Molner AS was EUR 2,338,793 (as per 31.12.2022, EUR 1,746,410). The total consolidated balance sheet increased by 25% compared to the total consolidated balance sheet at the end of 2022. As per 30.06.2023, consolidated current assets amounted to EUR 933,392 (as per 31.12.2022 EUR 816,776), which is 40% of total assets (as per 31.12.2022 47%). As per 30.06.2023 consolidated fixed assets amounted to EUR 1,405,401 (as per 31.12.2022 EUR 929,634), which is 60% of total assets (as per 31.12.2022 53%). As per 30.06.2023 the consolidated liabilities of J.Molner AS amounted to EUR 1,429,663 (as per 31.12.2022 EUR 1,484,767), which is 61% of the total balance sheet (as per 31.12.2022 85%). As per 30.06.2023 the consolidated equity was EUR 909,130 (as per 31.12.2022 EUR 261,643), which is 39% from total balance sheet (as per 31.12.2022 15%). As per 30.06.20233 it was decided to increase the voluntary reserve at the level of The J.Molner Company OÜ from long-term loan to align equity with the requirements of the Estonian Commercial Code.Previously the reserve amounted to EUR 750,000 and it was increased by EUR 1,065,000.

In January – June 2023 the Group's investments to fixed assets were EUR 455,849, including EUR 426,278 spent on research and development. Depreciation expenses for the first 6 months amounted to EUR 9,458.

In April 2023, J.Molner AS concluded an unsecured loan agreement which extended the existing credit facility of The J. Molner Company OÜ and under which J.Molner AS is entitled to draw down an additional loan with a principal of up to USD 2,000,000. The term of the loan is five years, and the interest is 7% p.a. As per 30.06.2023 the consolidated unaudited loan liabilities were EUR 1,206,153 (as per 31.12.2022 EUR 1,296,357), of which EUR 277,483 is short term liabilities (as per 31.12.2022 EUR 274,178) and EUR 928,670 (as per 31.12.2022 EUR 1,022,179) is long term liabilities. In the first half of 2023 the interest on loans was EUR 56,969. In the period 01.10.2022-31.12.2022 the interest on loans was EUR 26,431 EUR.

As per 30.06.2023 the consolidated unaudited sales revenue was EUR 270,769, in the period 01.10.2022-31.12.2022 the consolidated unaudited sales revenue was EUR 22,987. In January – June 2023 the consolidated unaudited loss was EUR 444,526, in period 01.10.2022-31.12.2022 the consolidated unaudited loss was EUR 318,612.

As per 30.06.2023 The Group had 24 employees, 1 member of the management board and 3 members of the supervisory board. In January – June 2023 the consolidated unaudited labour costs amounted to EUR 517,658, of which EUR 27,014 was the costs of the reserve provided to employees.

Financial Ratios	2023	2022
Current Ratio	1,86	1,77
Net Working Capital	432 399	354 188
EBITDA	-378 369	-392 813
Equity Ratio, %	38,87	14,98
Return on Total Assets, %	-164,17	-1386,05
Total Debt Ratio, x	0,61	0,85

Current Ratio = Current assets / Current liabilities
Net Working Capital = Current assets - Current liabilities
EBITDA = Operating profit + Depreciation and impairment loss
Equity Ratio = Equity / Cost of Assets *100
Return on Total Assets = Net Profit / Revenue *100
Total Debt Ratio = Liabilities / Total liabilities and owners` equity

The consolidated interim accounts

Consolidated statement of financial position
(In Euros)

	30.06.2023	31.12.2022	Note
Assets			
Current assets			
Cash and cash equivalents	675 300	722 796	2
Receivables and prepayments	248 704	84 592	3
Inventories	9 388	9 388	4
Total current assets	**933 392**	**816 776**	
Non-current assets			
Investments in subsidiaries and associates	263	263	
Receivables and prepayments	2 377	0	3
Property, plant and equipment	159 185	138 815	6
Intangible assets	1 243 576	790 556	7
Total non-current assets	**1 405 401**	**929 634**	
Total assets	**2 338 793**	**1 746 410**	
Liabilities and equity			
Liabilities			
Current liabilities			
Loan liabilities	277 483	274 178	8
Payables and prepayments	223 510	188 410	9,10
Total current liabilities	**500 993**	**462 588**	
Non-current liabilities			
Loan liabilities	928 670	1 022 179	8
Total non-current liabilities	**928 670**	**1 022 179**	
Total liabilities	**1 429 663**	**1 484 767**	
Equity			
Equity held by shareholders and partners in parent company			
Issued capital	1 686 001	1 686 001	
Share premium	612 327	612 327	
Other reserves	1 842 013	750 000	
Retained earnings (loss)	-2 786 685	-2 468 073	
Reporting period profit (loss)	-444 526	-318 612	
Total equity held by shareholders and partners in parent company	**909 130**	**261 643**	
Total equity	**909 130**	**261 643**	
Total liabilities and equity	**2 338 793**	**1 746 410**	

Consolidated income statement
(In Euros)

	01.01.2023 - 30.06.2023	01.10.2022 - 31.12.2022	Note
Revenue	270 769	22 987	11
Other income	4 636	2 719	
Work performed by entity and capitalized	262 793	74 418	
Raw materials and consumables used	-93 127	-61 429	
Other operating expense	-320 150	-259 686	12
Employee expense	-517 658	-170 603	13
Depreciation and impairment loss (reversal)	-9 458	-3 701	6,7
Other expense	-5 632	-1 219	
Operating profit (loss)	**-387 827**	**-396 514**	
Interest expenses	-56 969	-26 431	
Other financial income and expense	270	104 333	
Profit (loss) before tax	**-444 526**	**-318 612**	
Reporting period profit (loss)	**-444 526**	**-318 612**	
Profit (loss) from shareholders and partners in parent company	-444 526	-318 612	

* As J.Molner AS was founded using 100% of the shares in The J.Molner Company OÜ as non-monetary contribution, the consolidated comparative data is provided for the period 01.10.2022-31.12.2022.

Consolidated statement of cash flows
(In Euros)

	01.01.2023 - 30.06.2023	01.10.2022 - 31.12.2022
Cash flows from operating activities		
Receipts of sales of goods and rendering of services	205 681	24 999
Payments to suppliers for goods and services	-714 684	-373 983
Payments to employees	-264 531	-87 690
Other cash flows from operating activities	-87 090	-69 862
Total cash flows from operating activities	**-860 624**	**-506 536**
Cash flows from investing activities		
Purchase of property, plant and equipment and intangible assets	-93 452	-96 637
Other cash payments to acquire other financial investments	-2 377	0
Interest received	63	5
Total cash flows from investing activities	**-95 766**	**-96 632**
Cash flows from financing activities		
Loans received	908 894	0
Proceeds from issuing shares	0	698 328
Total cash flows from financing activities	**908 894**	**698 328**
Total cash flows	**-47 496**	**94 960**
Cash and cash equivalents at beginning of period	722 796	627 836
Change in cash and cash equivalents	**-47 496**	**94 960**
Cash and cash equivalents at end of period	675 300	722 798

Consolidated statement of changes in equity

(In Euros)

	Equity held by shareholders and partners in parent company				Total
	Issued capital	Share premium	Other reserves	Retained earnings (loss)	
01.10.2022	1 600 000	0	750 000	0	2 350 000
Reporting period profit (loss)	0	0	0	-2 786 685	-2 786 685
Issue of equity	86 001	612 327	0	0	698 328
31.12.2022	1 686 001	612 327	750 000	-2 786 685	261 643
Reporting period profit (loss)	0	0	0	-444 526	-444 528
Changes in reserves	0	0	1 092 013	0	1 092 013
30.06.2023	1 686 001	612 327	1 842 013	-3 231 211	909 130

* In the first half of 2023, the voluntary reserve increased in the amount of EUR 1,065,000 as of 30.06.2023 and the option reserve of 27,014 euros are reflected in changes in other reserves.

Notes

Note 1 Accounting policies

General information

The financial accounts of J.Molner AS for the first half of financial year 2023 have been prepared in accordance with the Estonian financial reporting standard. The Estonian financial reporting standard is established by the Accounting Act of the Republic of Estonia, whichis supplemented by the guidelines issued by the Accounting Standards Board.

This is a consolidated unaudited interim report of a small sized business.

The interim accounts have been prepared in Euros.

The principal accounting policies adopted are set out below.

Preparation of consolidated statements

In the consolidated report, all subsidiaries are consolidated line by line. All claims and liabilities within the group, transactions between group companies and unrealized profits and losses resulting from them have been eliminated.

Separate non-consolidated main statements of the consolidating entity (parent company) are published in the appendices to the interim consolidated financial statements. The parent company's basic reports have been prepared using the same accounting principles that have been applied in the preparation of the consolidated interim report, except for investments in subsidiaries and affiliates, which are reflected in theunconsolidated report using the acquisition cost method.

A company over which the parent company has control is considered a subsidiary company. A subsidiary is considered to be under the control of the parent company if the parent company directly or indirectly owns more than 50% of the subsidiary's voting shares or parts oris otherwise able to control the subsidiary's operational and financial policy.

Financial assets

The company has the following financial asset: cash. Financial assets are initially recognized at cost, this being the fair value of the consideration given. The acquisition cost includes all expenditures directly related to the purchase of the financial asset. All regular purchasesand sales of financial assets in market value are recognized on the transaction date. Following initial recognition, financial assets are measured based on their type either at fair value, at acquisition cost or at amortized cost.

Financial assets are derecognized when the company loses the right to receive cash flows from the financial asset or it transfers the financialasset, the cash flows from the financial assets and the majority of risks and rewards to other parties.

Cash and cash equivalents

Cash and cash equivalents in the balance sheet and in the cash flow statement include cash in bank accounts (except overdraft).

Foreign currency transactions and assets and liabilities denominated in a foreign currency

The company's functional currency is the Euro, all other currencies are deemed foreign currencies. Transactions denominated in foreign currenciesare recorded on the basis of the foreign currency exchange rates of the European Central Bank officially valid on the transaction date.

Monetary assets and liabilities (receivables paid in cash and loans) denominated in foreign currency are translated at balance sheet date into Euros based on the official foreign exchange rates of the European Central Bank. Gains and losses on foreign currency revaluations are recognized in the income statement in the corresponding accounting period. Non-monetary assets and liabilities denominated in foreigncurrencies, which are not carried at fair value (eg. prepayments, property, plant and equipment and intangible assets), are not revalued at balance sheet date, but instead are recorded with the exchange rate of the European Central Bank that was valid on the transaction date.

Shares of subsidiaries and associates

Shares or parts of subsidiaries and affiliates are recorded at acquisition cost. The acquisition cost is considered to be paid upon acquisitionthe amount of money or the fair value of the other consideration to be transferred and expenses directly related to the acquisition.

The subsidiary company has not been consolidated, because the consolidated figures, excluding transactions between themselves, are notgreater than those of a small indicator of the balance sheet volume and net turnover of the consolidation group, to which 20% is added.

Receivables and prepayments

Accounts receivable are receivables arising from ordinary business transactions of the company. Accounts receivables are recorded using theamortized cost method (i.e., nominal value less impairment loss).
The collectability of the accounts receivable is considered separately by each customer. Accounts receivable, which partly or fully are not expected to be collected, are expensed and reported in the income statement as "Other operating expense". Receivables, collection ofwhich is not feasible nor economically justified, are considered to be non-collectible and written-off from the balance sheet.
Receipt of doubtful receivables previously written down is recognized as a decrease in the expense of doubtful receivables.

Inventories

Inventories are initially recognized at cost which comprises costs of purchase, production costs and other costs incurred in bringing theinventories to their present location and condition.

Inventories are expensed using the FIFO method.

Inventories are measured in the balance sheet at the lower of cost or net realizeble value. Net realizable value is the estimated selling price of a product in the ordinary course of business less the estimated costs of completion and those necessary to make the sale.

Plant, property and equipment and intangible assets

Property, plant and equipment are assets used in the company's own business activities with a useful life exceeding one year and the cost ofat least 1 350 Euros.

A property, plant and equipment is initially recorded at cost which comprises the purchase price and other costs directly attributable to the acquisition that are necessary for bringing the asset to its operating condition and location. Property, plant and equipment is carried in the balance sheet at acquisition cost, less accumulated depreciation and any accumulated impairment losses.

If the major components of an item of property, plant and equipment have significantly different useful lives, these components shall be recognized initially as separate items of property, plant and equipment and separate depreciation rates shall be assigned to them dependingon their useful lives.

An intangible asset is initially recorded at a cost which comprises the purchase price and other costs directly attributable to the acquisition. An intangible asset is carried in the balance sheet at its cost, less accumulated amortization, and any accumulated impairment losses.

Pharmaceutical products in development are recorded as unfinished projects. Once products in development are approved for sale, the amounts will be allocated to product rights and will be amortized. Unfinished projects include also product acquisition costs representing productrights obtained from third parties possessing regulatory approvals in respective markets, however, production of which has not yet started. Product acquisition costs are reclassified as intangible assets in use and will be amortized once products are commercialized.

Minimal acquisition cost 1350

Useful life by assets group (years)

Assets group name	Useful life
Machinery and equipment	5-20
Other property, plant and equipment	2-5
Concessions, patents, licenses, trademarks	10

The company performs an impairment test at each balance sheet date on those assets where there is any indication of potential impairment.

An impairment test is performed to determine the recoverable amount of an asset, which is the higher of the two indicators – fair value of anasset (less costs to sell) and its value in use. Value in use is the present value of estimated future cash flows expected to arise from the useof an asset and from the disposal at the end of its useful life.

When an impairment test is not feasible for an individual asset beceuse the cash flows being generated by the asset are indistinguishable fromthe cash flows of the rest of the entity, an impairment test shall be performed for the cash-generating unit to which the asset belongs.

Assets are written down to their recoverable amount if the recoverable amount of the asset is lower than its carrying amount. The impairmentloss is recognized on an accrual basis as an expense in the income statement under "Depreciation and impairment loss".

Products in development are subject to the annual impairment testing. These valuations reflect, among other things, the impact of changes to the development programs, the projected development and regulatory time frames and the current competitive environment.

Recording of property, plant and equipment and intangible assets is finished in case of disposal of the asset or in case the economic benefitsare no longer expected from use or sale of the asset.

The straight-line method is used for depreciating property, plant, and equipment. The depreciation rates are assigned to each item of property, plant and equipment or major component separately, based on the useful life of the specific item. The straight-line method is used for amortizing intangible assets. The amortization rates are assigned to each item of intangible asset, based onthe useful life of the specific item.

Leases

Lease transactions, where all material risks and rewards from the ownership of an asset are transferred to the lessee, are treated as finance lease. All other lease transactions are treated as operating leases. Operating lease payments are recorded as expenses based on straight-line method over the entire lease period.

Financial liabilities

Financial liabilities (trade payables, received loans, accrued expenses) are initially measured at cost, which is the fair value of considerationreceived. The initial cost of financial liabilities includes all direct transaction costs. Subsequently the financial liabilities are recorded at amortized cost.

The amortized cost of short-term liabilities, in general, is equal to their nominal value. Therefore, they are recognized in the amount required tosettle the liability. For calculating the amortized cost of long-term financial liabilities, the effective interest rate method is used. A financial liability is derecognized when the obligation under the liability is discharged, cancelled, or expires.

A financial liability if classified as long-term in the balance sheet if it is due more than 12 months after the balance sheet date. All other liabilitiesare classified as short-term.

Revenue recognition

Revenue from the sale of goods is recognized when all significant risks related to ownership of goods are transferred to the buyer, the sales revenue and transaction costs can be reliably measured and the receipt of payment from the transaction is probable. Revenue from services is recognized in the period the services are rendered, assuming that the receipt of payment from the transaction is probable and the sales revenue and the expenses related to providing the services can be reliably measured.

Taxation

According to the Income Tax Act, Estonian companies are not subject to pay income tax on the profit. Income tax is paid on distribution of dividends, fringe benefits, gifts, donations, receptions costs, expenses not related to business activities and transfer pricing adjustments.The tax rate is 20/80 of the taxable amount.

Related parties

The following are considered as related parties in the preparation of the interim report for J. Molner AS:

- owner;
- members of management board;
- companies under control or significant influence of aforementioned individuals or their close relatives.

Note 2 Cash and cash equivalents

(In Euros)

	30.06.2023	31.12.2022
Cash and cash equivalents	675 300	722 796
Total cash and cash equivalents	**675 300**	**722 796**

Note 3 Receivables and prepayments

(In Euros)

	30.06.2023	Allocation by remaining maturity	
		Within 12 months	1 - 5 years
Accounts receivable	118 189	118 189	0
Accounts receivables	118 189	118 189	0
Tax prepayments and receivables	12 195	12 195	0
Prepayments	120 697	118 320	2 377
Deferred expenses	90 318	90 318	0
Other paid prepayments	30 379	28 002	2 377
Total receivables and prepayments	**251 081**	**248 704**	**2 377**

	31.12.2022	Allocation by remaining maturity	
		Within 12 months	1 - 5 years
Accounts receivable	2 622	2 622	0
Accounts receivables	2 622	2 622	0
Tax prepayments and receivables	16 855	16 855	0
Prepayments	65 115	65 115	0
Deferred expenses	22 814	22 814	0
Other paid prepayments	42 301	42 301	0
Total receivables and prepayments	**84 592**	**84 592**	**0**

Note 4 Inventories

(In Euros)

	30.06.2023	31.12.2022
Raw materials	**9 388**	**9 388**
Raw materials	9 388	9 388
Total inventories	**9 388**	**9 388**

Note 5 Shares of subsidiaries

(In Euros)

Shares of subsidiaries, general information

Subsidiary's registry code	Name of subsidiary	Country of incorporation	Principal activity	Ownership interest (%)	
				31.12.2022	30.06.2023
16049566	The J. Molner Company OÜ	Estonia	Research and development in the field ofbiotechnology	100	100
87-2116750	The J. Molner Company LLC	United States of America	Wholesale	0	100

Note 6 Property, plant and equipment

(In Euros)

	Computers and computer systems	Other machinery and equipment	Machinery and equipment	Total
01.10.2022				
Carried at cost	0	114 153	114 153	114 153
Accumulated depreciation	0	-21 156	-21 156	-21 156
Residual cost	0	92 997	92 997	92 997
Acquisitions and additions	6 943	43 398	50 341	50 341
Other acquisitions and additions	6 943	43 398	50 341	50 341
Depreciation	-231	-4 292	-4 523	-4 523
31.12.2022				
Carried at cost	6 943	157 551	164 494	164 494
Accumulated depreciation	-231	-25 448	-25 679	-25 679
Residual cost	6 712	132 103	138 815	138 815
Acquisitions and additions	19 301	10 270	29 571	29 571
Other acquisitions and additions	19 301	10 270	29 571	29 571
Depreciation	-1 503	-7 698	-9 201	-9 201
30.06.2023				
Carried at cost	26 244	167 821	194 065	194 065
Accumulated depreciation	-1 734	-33 146	-34 880	-34 880
Residual cost	24 510	134 675	159 185	159 185

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Verastem, Inc., d.b.a. Verastem Oncology

Physical Address: 117 Kendrick Street, Suite 500

City: Needham State: MA Zip: 02494

Mailing Address (if different from physical address): 117 Kendrick Street, Suite 500

City: Needham State: MA Zip: 02494

Telephone: (781) 292-4200 Website: Verastem.com

Name of Designated Representative (DR): Robert Pintar

Licensing Company Email: Statelicensing@verastem.com DR Email: bpintar@verastem.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: specialty distributor's, specialty pharmacies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: New Facility- no suppliers sold, dispensed or distributed w/i last

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Verastem, Inc., d.b.a. Verastem Oncology

Corporation Name: Verastem, Inc., d.b.a. Verastem Oncology

Mailing Address: 117 Kendrick Street, Suite 500

City: Needham State: MA Zip: 02494

Telephone: (781) 292-4200 Email: Statelicensing@verastem.com

Contact Person Name: Robert Pintar

Date of SEC Registration: 7/26/2011 | SEC Registration Number: 1526119 | Stock Exchange Symbol: VSTM

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Verastem, Inc., d.b.a. Verastem Oncology
Facility Name

Daniel Paterson
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/19/23
Date

Board Use Only	Date Received: 12/11/23	Amount: $1,000-check 288

OWNERSHIP

Verastem, Inc. dba Verastem Oncology ("Verastem") is a publicly traded virtual manufacturer of pharmaceutical products located in Needham, MA. Verastem is incorporated in the state of Delaware.

COMPANY INFORMATION

Verastem, Inc. dba Verastem Oncology
117 Kendrick Street, Suite 500
Needham, MA 02494
Phone: (781) 292-4200
statelicensing@verastem.com

CORPORATE OFFICERS

Daniel Paterson, President and Chief Executive Officer

117 Kendrick Street, Suite 500
Needham, MA 02494
(781) 292-4200

Jonathan A. Pachter, Chief Scientific Officer 117 Kendrick Street, Suite 500
Needham, MA 02494
(781) 292-4200

Daniel Calkins, VP of Finance
117 Kendrick Street, Suite 500
Needham, MA 02494
(781) 292-4200

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VERASTEM, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF NOVEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4853179 8300

SR# 20233943396

Authentication: 204563829

Date: 11-09-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

VERASTEM, INC, DBA VERASTEM ONCOLOGY
117 KENDRICK STREET, SUITE 500
NEEDHAM, MA 02494

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: MA0001076

Type: Virtual Manufacturer

Issue Date: 07/18/2023

Expiration Date: 08/22/2024

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

An official website of the Commonwealth of Massachusetts Here's how you know

Mass.gov Office of Health and Human Services (EOHHS) License Verification Site

License Information

License Type:	Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration
License Number:	MA0001076
Status:	Current
Organization Name:	VERASTEM, INC, DBA VERASTEM ONCOLOGY
Expiration Date:	August 22, 2024
Address:	117 KENDRICK STREET SUITE 500 NEEDHAM, MA 02494

Compliance Actions/Fines

There are no public compliance actions or fines against this license/registration record.

Verification of Licensure

To generate a Verification of Licensure for this license/registration record, please click the "Generate Verification of Licensure" button below.

Generate Verification of Licensure

Disclaimer: The information contained in this website ("website content") is made available as a public service by the Massachusetts Department of Public Health (the Department). The Department considers this information to constitute primary source verification. Click here for full disclaimer.

<< Back to Search Page

How To Get Help:

Mass.gov Resources

eLicensing User Guide
Bureau of Health Professions Licensure
Office of Local and Regional Health
Department of Public Health
Phone: (800) 414-0168

BHPL eLicensing Support Resources

Online: eLicensing Support Request Form
Email: dph.elicensing_support@mass.gov

DO NOT provide your Social Security Number or **Date of Birth** when contacting the eLicensing Support Desk online or by email

Description of Operations

Verastem's Inc. dba Verastem Oncology ("Verastem") is a Virtual Manufacturer based in Massachusetts. Verastem's products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors and Specialty Pharmacies by their Third-Party Logistics Provider, Integrated Commercialization Solutions,, who is licensed to ship pharmaceutical products into your state. Verastem Inc. is publicly traded on the NASDAQ (VSTM). Verastem Inc. was incorporated in the State of Delaware on 8/4/2010.

Contract Manufacturer Information:
Verastem will be using the contract manufacturer(s) below to produce our product:

Packaging Coordinators Inc.
4545 Assembly Drive
Rockford, IL 61109
PH: (815) 218-2733
FEIN: 3001670824

Haupt Pharma Amareg GmbH
Donaustaufer StraBe 378
Regensburg, Germany D-93055
PH: +49 941 4601-332
FEIN: 3008293991

Cambrex
30 North Jefferson Road
Whippany, NJ 07981
PH: (973) 428-4348
FEIN: 2211084

At no time do Verastem's Contract Manufacturers own the product, contract with Verastem's customers, invoice, nor sell Verastem's product. Verastem's products are not Controlled Substances.

Labeler Code: 71779 Verified 8.15.23

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC ("ICS") acts as Verastem's Third Party Logistics (3PL) provider to manage the storage and distribution of Verastem's product to Specialty Distributors and Specialty Pharmacies throughout the United States.

Integrated Commercialization Solutions, LLC
420 International Blvd., Suite 500
Brooks, KY 40109
PH: (469) 400-8663

Integrated Commercialization Solutions, LLC
1195 Trademark Drive, Suite 102
Reno, NV 89521
PH: (469) 400-8663

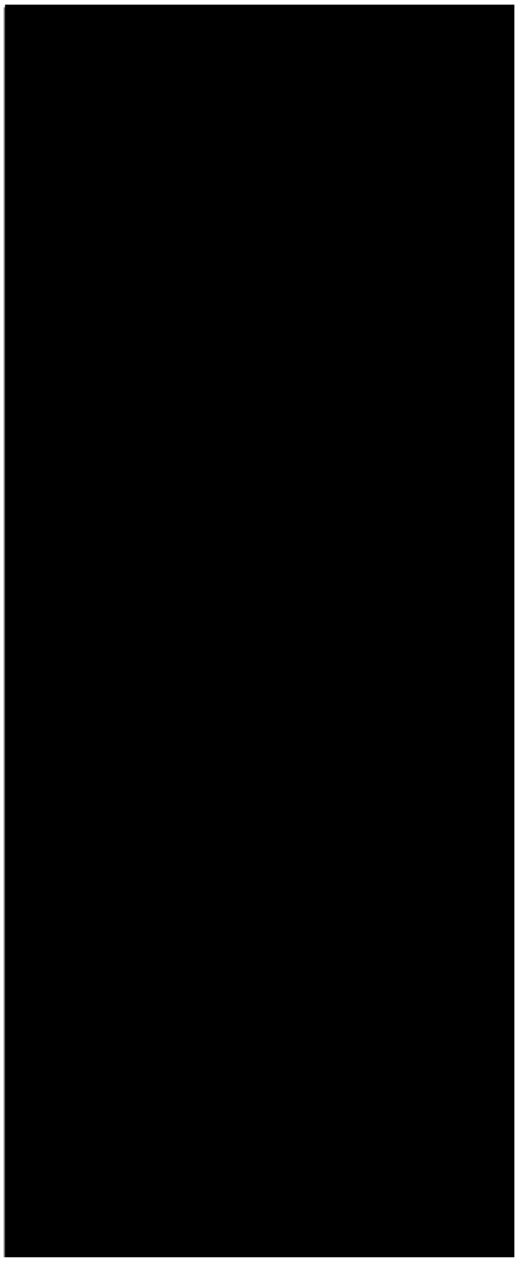
Verastem's Inc. dba Verastem Oncology ("Verastem") hours of operation are 8:00 am – 5:00pm PST Monday through Friday.

Drug Catalog

NDC Code	Proprietary Name	Nonproprietary Name	Strength	Dosage Form
71779-105-01	Copiktra	Duvelisib	5mg	Capsule
71779-115-01	Copiktra	Duvelisib	15mg	Capsule
71779-125-01	Copiktra	Duvelisib	25mg	Capsule

Employee list confidential:
The content of this document is confidential and it not to be used beyond its intended use.
Confidential Information - Do Not Distribute

Last Name	First Name
[redacted]	



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **October 24, 2023**

Verastem, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-35403**	**27-3269467**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

117 Kendrick Street, Suite 500, Needham, MA	**02494**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(781) 292-4200**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	VSTM	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

Chief Financial Officer Appointment

On October 24, 2023, the board of directors (the "Board") of Verastem, Inc. (the "Company") appointed Daniel Calkins as Chief Financial Officer of the Company. As previously disclosed, Mr. Calkins has served as the Company's principal financial officer and principal accounting officer on an interim basis since October 31, 2022.

In connection with his appointment, the Company entered into an employment agreement with Mr. Calkins (the "Agreement"), dated as of October 24, 2023, governing the terms of Mr. Calkins's employment for an indefinite term. The Agreement replaces and supersedes any prior existing employment agreement between Mr. Calkins and the Company. Under the Agreement, Mr. Calkins will receive an initial annual base salary of $300,000 and is eligible for an annual bonus target of 35% of his base salary, which will be pro-rated for the remainder of the year ended December 31, 2023, with Mr. Calkins' 2023 annual bonus for the period prior to October 19, 2023 determined on the terms as in effect prior to October 19, 2023 and pro-rated for that portion of the year.

Pursuant to the terms of the Agreement, on October 24, 2023 (the "Grant Date"), the Company granted Mr. Calkins an option to purchase 25,000 shares of its common stock at an exercise price equal to $6.89 per share, the closing price of the Company's common stock as reported by the Nasdaq Capital Market on the Grant Date, to vest as to 25% of the shares on the one-year anniversary of the Grant Date, and as to an additional 6.25% of the shares at the end of each successive three-month period following the first anniversary of the Grant Date until the fourth anniversary of the Grant Date, subject to Mr. Calkins' continuing service with the Company on the applicable vesting date.

Under the Agreement and subject to Mr. Calkins' execution and non-revocation of an effective release of claims, if Mr. Calkins' employment is terminated by the Company without Cause (as defined in the Agreement) or by Mr. Calkins for Good Reason (as defined in the Agreement), he will be entitled to receive the following severance benefits: (i) nine months of base salary continuation, (ii) if Mr. Calkins exercises his right to continue participation in the Company's health and dental plans under the federal law known as COBRA, a monthly cash amount equal to the full premium cost of that participation for nine months (or, if earlier, until the time when Mr. Calkins becomes eligible to enroll in the health or dental plan of a new employer), and (iii) any base salary earned, but not yet paid, through the date of termination and any bonus which has been awarded, but not yet paid, on the date of termination.

If Mr. Calkins' employment is terminated by the Company without Cause or by Mr. Calkins for Good Reason, in either case within 90 days prior to or within 18 months following, a Change of Control (as defined in the Agreement), subject to Mr. Calkins' execution and non-revocation of an effective release of claims, he will instead be entitled to receive the following severance benefits: (i) a lump sum amount equal to 12 months of his base salary, (ii) if Mr. Calkins exercises his right to continue participation in the Company's health and dental plans under the federal law known as COBRA, a monthly cash amount equal to the full premium cost of that participation for 12 months (or, if earlier, until the time when Mr. Calkins becomes eligible to enroll in the health or dental plan of a new employer), (iii) a pro-rata portion of his target annual bonus amount for the year in which the termination occurs, calculated based on the number of days Mr. Calkins was employed by the Company in such year, (iv) accelerated vesting of all outstanding stock options, restricted stock and restricted stock units held by Mr. Calkins that, by their terms, vest only based on the passage of time, and (v) any bonus which has been awarded, but not yet paid on the date of termination. In addition, upon a Change

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: AnovoRx Distribution, LLC

Physical Address: 17500 S 40th Street, Building B600B

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): 1710 N Shelby Oaks Drivs, Suite 2

City: Memphis State: TN Zip: 38134

Telephone: 844-288-5007 Website: anovorx.com

Name of Designated Representative (DR): Lorin Farr

Licensing Company Email: Officialcontact@anovorx.com DR Email: Lorin.Farr@anovorx.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Orphan and Rare Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Specialty Prescription Drug

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

John B. Peters

Original Signature (electronic, copies or stamps not accepted)

07/06/2023

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: AnovoRx Distribution, LLC is sole provider to date; applicant just recently open for business
Address: 1710 N Shelby Oaks Dr STE 6 City: Memphis State: TN Zip: 38134

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee / AnovoRx Distribution, LLC
Parent Company (if any): AnovoRx Holdings, Inc.
Corporation/Organization Name: AnovoRx Distribution, LLC
Mailing Address: 1710 N Shelby Oaks Drive, Suite 2
City: Memphis State: TN Zip: 38134
Telephone: 901-201-5470 Email: Officialcontact@anovorx.com
Contact Person Name: Cathy Bellehumeur

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

AnovoRx Distribution, LLC

Facility Name

Jon B. Peters, President/CEO

Print Name of Authorized Person Submitting Application

Jon B. Peters

Original signature of Authorized Person (copies or stamps not accepted)

07/06/2023

Date

Board Use Only	Date Received: 8/21/23	Amount: 1000-CK-5575

anovo

ANOVORX GROUP, LLC OFFICER and DIRECTOR LIST

The applicant pharmacy is owned by AnovoRx Group, LLC.
AnovoRx Group, LLC is a TN Limited Liability Company. Its Tax ID # 45-5299748.
AnovoRx Group, LLC is owned 100% by AnovoRx Holdings, Inc., Tax ID # 46-1775496.
AnovoRx Group, LLC has three Officers and there is only one member of its Board of Directors.
The Officers of AnovoRx Group, LLC are Jon B. Peters, President and CEO; Kyle P. Truitt, SVP and COO; Jason T. Shackelford, VP and CFO. The sole member of the Board of Directors of AnovoRx Group, LLC is Jon B. Peters.

NAME	ROLE	HOME ADDRESS	CELL PHONE	DOB	EMAIL	SSN	WORK ADDRESS	WORK PHONE	Pharmacist or Prescriber?	% ownership of Applicant
Jon B. Peters	President/ CEO/Sole Member Board of Directors	[redacted]			Jon.peters @anovorx.com	[redacted]	1710 N Shelby Oaks DR STE 2 Memphis TN 38134	901-201-5484	no	0%
Kyle P. Truitt	Sr. VP and COO	[redacted]			Kyle.truitt @anovorx.com		1710 N Shelby Oaks DR STE 2 Memphis TN 38134	901-979-1020	no	0%
Jason T Shackelford	VP and CFO	[redacted]			Jason.shackelford @anovorx.com		1710 N Shelby Oaks DR STE 2 Memphis TN 38134	901-390-4539	no	0%

AnovoRx Group, LLC
OWNERS LIST

Name of Owner	% Ownership Of AnovoRx Group, LLC
AnovoRx Holdings, Inc. Address: 1710 N Shelby Oaks Dr STE 2 Memphis TN 38134 PH: 901-201-5470 FEIN: 46-1775496 No Trade name	**100%**
TOTAL	**100%**

ANOVORX HOLDINGS, INC. % OWNERSHIP, SHAREHOLDERS AND SHARE ROSTER
FIVE PERCENT AND MORE OWNERS

Name	% Ownership Holdings (the Parent of the Applicant)	=	Voting Shares	Non-Voting Share(s)	Total Shares on a Fully Diluted Basis
Joel Kimbrough Address: [redacted] Pharmacist: NO Business Address: NONE Business PH: NONE	**13.5%**	=	**7,500**	6,000	13,500
Jon Peters [redacted] Pharmacist: NO Business Address: 1710 N Shelby Oaks Dr Memphis TN 38134 Business PH: 901-201-5484	**13.5%**	=	**7,500**	6,000	13,500
Equity Partners XX (20), LLC Address: 5597 St. Joseph Fairway Memphis, TN 38120-2211 PH: 901-685-6218 DOB: N/A FEIN: 46-1252638 Pharmacist: NO Business Address: 5597 St. Joseph Fairway Memphis, TN 38120- Business PH: 901-685-6218	**13.5%**	=	**7,500**	6,000	13,500
Diane Callahan [redacted] Pharmacist: NO Business Address: NONE Business PH: NONE	**6%**	=	**-0-**	6,000	6,000
TPG Growth V Amplifier, L.P. Address: 301 Commerce Street, Suite 3300	**40%**	=	**20,000**	20,000	40,000

CONFIDENTIAL

Fort Worth, TX 76102 PH: 817-871-4000 DOB: N/A FEIN: 87-3400515 Pharmacist: NO Business Address: 301 Commerce Street, Suite 3300 Fort Worth, TX 76102 Business PH: 817-871-4000			
Assorted other owners each with less than a 5% interest, aggregating to 13.5%	**13.5%** **=7,500**	6,000	6,000
TOTAL	**100%** **=** **50,000**	**50,000**	**100,000**

CONFIDENTIAL

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

ANOVORX GROUP, LLC - LEGAL DEPT
LEGAL DEPARTMENT
SUITE 2
1710 N SHELBY OAKS DR
MEMPHIS, TN 38134

April 19, 2023

Request Type: Certificate of Existence/Authorization
Request #: 0526451

Issuance Date: 04/19/2023
Copies Requested: 1

Document Receipt

Receipt # : 008060667 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3849640823 — $20.00

Regarding: **AnovoRx Distribution, LLC**

Filing Type:	Limited Liability Company - Domestic	Control # :	706058
Formation/Qualification Date:	01/11/2013	Date Formed:	01/11/2013
Status:	Active	Formation Locale:	TENNESSEE
Duration Term:	Perpetual	Inactive Date:	
Business County:	SHELBY COUNTY		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

AnovoRx Distribution, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 060161619

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 02/08/2023
Receipt Number: 2023147853
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO
W003768

EXPIRES
10/31/2024

Issued to : AnovoRx Distribution, LLC
AnovoRx Distribution, LLC
1710 N SHELBY OAKS DR SUITE 2 MEMPHIS, TN 38134

AnowoRx Distribution, LLC
17500 S 40TH STREET BUILDING B 600B
CHANDLER, AZ 85226

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : AnovoRx Distribution, LLC
LICENSE NUMBER : W003768
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 43BSBJA9024

Application/License No. _____

AnovoRx Distribution, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 17500 S. 40th Street, Building B, Suite B600B, Chandler, AZ 85226 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Hartford Plaza, Hartford, CT 06155-0001 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 8, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

43BSBJA9024

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day Of May, 2023.

APPLICANT/PRINCIPAL

AnovoRx Distribution, LLC

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Michael A. McDaniel , Attomey-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Licensed Agent No. 3574505
Richard H. Whitley

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MCDANIEL WHITLEY INC
Agency Code: 43-484036

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Michael A. McDaniel

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 43BSBJA9024
Naming AnovoRx Distribution, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of May 8, 2023.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

anovo

Dedicated.
Exclusive.
Unique.

LIST OF EMPLOYEES AT LOCATION

The below is the only employee at this time at this location. There are no agents, independent contractors, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Lorin Farr - Designated Representative

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Y

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: AnovoRx Distribution, LLC

Pharmacy/Wholesaler License # (if applicable): W003768

Physical Address: 17500 South 40th St, Building B, Suite B600B

City: Chandler State: Arizona Zip: 85226

Mailing Address (if different from physical address): 1710 N Shelby Oaks Drive, Suite 2

City: Memphis State: Tenesse Zip: 38134

Telephone: 901-201-5470 Website: anovorx.com

Licensing Company Email: Officialcontact@anovorx.com

Section 2: Personal Information

First: Lorin Middle: Richard Last: Farr

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Gilbert State: AZ Zip: 85297

Telephone: [redacted] Email: Lorin.Farr@anovorx.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chandler Gilbert Community College		08/07 - 12/13	
Address	**City**	**State**	**Zip**
2626 E Pecos Rd	Chandler	AZ	85225
Diploma/Degree obtained, if any			
Associates in Arts			

School Name		From - To (MM/YY – MM/YY)	
Gilbert High School		08/99 - 05/04	
Address	**City**	**State**	**Zip**
1101 E Elliot Rd	Gilbert	AZ	85234
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/14 - 7/23	[redacted]	Gilbert	AZ	85297
02/87 - 10/14		Gilbert	AZ	85234

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
AnovoRx Distribution			02/23 - 07/23	
Business Address		**City**	**State**	**Zip**
17500 South 40th St, Building B, Suite B600B		Chandler	AZ	85226
Phone	**Title**		**Number of Employed Hours**	
901-201-5470	Wholesale Distribution Manager		Full Time 40hrs/wk	

Description of Duties

Start up new wholesale facility. Organize and maintain warehouse. Setup relations with vendors and order sufficient supplies for the facility and shipping.

Business Name			From - To (MM/YY – MM/YY)	
LSG Sky Chefs			06/22 - 01/23	
Business Address		**City**	**State**	**Zip**
3555 S 28th St		Phoenix	AZ	85040
Phone	**Title**		**Number of Employed Hours**	
602-737-5895	Warehouse Supervisor		Full Time 40hrs/wk	

Description of Duties

Reported weekly KPI's to Materials Manager including, FIFO Accuracy, FIORI/SAP Scanning Accountability, Cycle Count Accuracy.

Business Name			From - To (MM/YY – MM/YY)	
The Compounding Center			06/20 - 12/21	
Business Address		**City**	**State**	**Zip**
1110 E McDowell Rd		Phoenix	AZ	85006
Phone	**Title**		**Number of Employed Hours**	
480-691-4972	Warehouse Supervisor		Full Time 40hrs/wk	

Description of Duties

Supervised shipping and receiving, distribution, and workplace safety.
Revised and developed procedures to reduce risk and achieve compliance.

Business Name			From - To (MM/YY – MM/YY)	
Diplomat Specialty Pharmacy			04/19 - 04/20	
Business Address		**City**	**State**	**Zip**
485 N Juniper Dr		Chandler	AZ	85226
Phone	**Title**		**Number of Employed Hours**	
480-680-2676	Lead Certified Pharmacy Technician		Full Time 40hrs/wk	

Description of Duties

Stocked, labeled and inventoried medication to keep accurate records.
Assisted in preparation, distribution, and storage of pharmaceuticals.

Business Name			From - To (MM/YY – MM/YY)	
Magellan			11/18 - 04/19	
Business Address		**City**	**State**	**Zip**
4801 E Washington St		Phoenix	AZ	85034
Phone	**Title**		**Number of Employed Hours**	
480-781-7851	Certified Pharmacy Technician Supervisor		Full Time 40hrs/wk	

Description of Duties

Resolved non-routine issues like third-party billing, computer system and customer service issues.
Answered incoming phone calls and addressed questions from customers and healthcare providers.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
GenRx			07/17 - 08/18	
Business Address		City	State	Zip
8010 E. McDowell Rd, Suite 205		Scottsdale	AZ	85257
Phone	Title		Number of Employed Hours	
866-453-6143	Certified Pharmacy Technician Supervisor		Full Time 40hrs/wk	
Description of Duties				
Helped pharmacists clear problematic prescriptions and address customer questions to keep pharmacy efficient. Communicated with prescribers to verify medication dosages, refill authorizations and patient information.				

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			07/16 - 08/17	
Business Address		City	State	Zip
1301 S Crismon Rd		Mesa	AZ	85209
Phone	Title		Number of Employed Hours	
800-471-7867	Lead Certified Pharmacy Technician		Full Time 40hrs/wk	
Description of Duties				
Counted, measured, and compounded medications following standard procedures. Worked with computerized and automated systems for dispensing medications.				

Business Name			From - To (MM/YY – MM/YY)	
Catamaran			04/13 - 03/16	
Business Address		City	State	Zip
4801 E Thistle Landing Dr		Phoenix	AZ	85044
Phone	Title		Number of Employed Hours	
800-356-3477	Senior Certified Pharmacy Technician		Full Time 40hrs/wk	
Description of Duties				
Resolved non-routine issues like third-party billing, computer system and customer service issues. Answered incoming phone calls and addressed questions from customers and healthcare providers.				

Business Name			From - To (MM/YY – MM/YY)	
Express Scripts			10/11 - 03/13	
Business Address		City	State	Zip
7909 S Hardy Dr # 106		Tempe	AZ	85284
Phone	Title		Number of Employed Hours	
480-961-1051	Lead Certified Pharmacy Technician		Full Time 40hrs/wk	
Description of Duties				
Counted, measured, and compounded medications following standard procedures. Restocked automated medication dispensing equipment.				

Business Name			From - To (MM/YY – MM/YY)	
Fry's Food & Drug			08/07 - 04/11	
Business Address		City	State	Zip
825 W University Dr		Mesa	AZ	85201
Phone	Title		Number of Employed Hours	
480-844-7195	Lead Certified Pharmacy Technician		Full Time 40hrs/wk	
Description of Duties				
Stocked, labeled and inventoried medication to keep accurate records. Answered incoming phone calls and addressed questions from customers and healthcare providers.				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/31/2013	12/18/2013	AZ	Gilbert	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2013-CT-0018576	Gilbert Municipal Court

Reason/Charge
13-1802.A.1 Theft

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Defendant	

Name of Business/Industry/Entity
Mark Allan Jordan

Provide explanation below:

A lawn ornament was taken from a residence as a dare. The item was returned. The owner of the property pressed charges. Fines were payed, and after the probation period the charge was Set Aside.

Original Signature (electronic, copies or stamps not accepted)

7/26/2023
Date

RESPONSE TO SECTION 8 QUESTION #1

1639

GILBERT MUNICIPAL COURT
Records History for
Farr, Lorin Richard, DOB: 2/14/1986

CASE NUMBER: 2013CT18576

CHARGE: 13-1802.A.1 THEFT
VIOLATION DATE: 10/31/2013
DISPOSITION: Guilty-Resp (11)
DOMESTIC VIOLENCE: No
PROBATION: Unsupervised **MONTHS:** 36

FINE AMOUNT: $373.50
BALANCE DUE: $0.00
DISPOSITION DATE: 12/18/2013

CASE STATUS: Disposed
TRIED AS AN ADULT: YES

PROBATION COMPLETED: No
PROBATION TERMS COMPLETED: No

JAIL(# in days):

OTHER SENTENCING:

Is there any pending court action? ☐ Yes ☒ No

Have all fines (and/or restitution) been paid? ☒ Yes ☐ No

NAME OF AGENCY: Gilbert Municipal Court

Signature: Woodman **Official Title:** Office Assistant

Date: 6/26/2015

Please note:

Gilbert Municipal Court does not handle Felony Cases

Gilbert Municipal Court does not have minute entries

If Warrant and/or Probation information is not displayed this means it is not available

I, Lorin Farr, **certify that as the designated representative for**

AnovoRx Distribution, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LF I am at least 21 years of age;
3. LF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lorin Farr

Print Name (First, Last)

Lorin Richard Farr

Original Signature (electronic, copies or stamps not accepted)

7/26/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lorin Farr

Print Name (First, Last)

Lorin Richard Farr

Original Signature (electronic, copies or stamps not accepted)

7/26/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Lorin Farr, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Lorin Richard Farr

Original Signature

7/26/2023

Date

Subscribed and Sworn to before me this 26 day of July 2023.

Notary Public Signature

EMILY ERVIN
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
My Commission Expires March 11, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

4

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler AnovoRx Distribution, LLC

Physical Address 17500 South 40th St., Building B, Suite B600B

City Chandler State AZ Zip 85226

Mailing Address (if different from physical address) 1710 N Shelby Oaks Drive, Suite 2

City Memphis State TN Zip 38134-7403

Telephone 901-201-5470 Website anovorx.com

Licensing Company Email Officialcontact@anovorx.com

Section 2: Personal Information

First Joel Middle Ray Last Kimbrough

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Germantown State TN Zip 38139-2502

Telephone [redacted] Email Joel.kimbrough@anovorx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Alabama		09/76 - 05/80	
Address	**City**	**State**	**Zip**
1 Harrison Plaza	Florence	AL	35632
Diploma/Degree obtained, if any			
BS Accounting			

School Name		From - To (MM/YY – MM/YY)	
Cherokee Vocational High School		09/72 - 05/76	
Address	**City**	**State**	**Zip**
850 High School Drive	Cherokee	AL	35616
Diploma/Degree obtained, if any			
Academic High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/20 - Present	[redacted]	Germantown	TN	38139
03/18 - 12/20		Germantown	TN	38139
07/14 - 02/18		Eads	TN	38028
10/11 - 06/14		Cordova	TN	38018
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AnovoRx Group, LLC			5/12 - Present	
Business Address		**City**	**State**	**Zip**
1710 N Shelby Oaks Drive, Suite 2		Memphis	TN	38134
Phone	**Title**			
901-201-5470	Director			
Description of Duties				
Member of the Board of Directors				

Business Name			From - To (MM/YY – MM/YY)	
The Barnett Group			01/09 - 09/17	
Business Address		**City**	**State**	**Zip**
7906 Players Forest Drive		Memphis	TN	38113
Phone	**Title**			
901-365-3447	VP of Business Development			
Description of Duties				
Member of LLC and developed Pharmacy Benefit Practice				

Business Name			From - To (MM/YY – MM/YY)	
Veritas Collaborative			09/12 - 01/19	
Business Address		**City**	**State**	**Zip**
4024 Stirrup Creek Drive		Durham	NC	27703
Phone	**Title**			
655-875-5812	Director			
Description of Duties				
Member of Board of Directors				

Business Name			From - To (MM/YY – MM/YY)	
Cellarian, Inc.			05/14 - 09/18	
Business Address		**City**	**State**	**Zip**
111 Vision Park Blvd., Suite 100		Shenandoah	TX	77384
Phone	**Title**			
866-766-6310	Director			
Description of Duties				
Member of Board of Directors				

Business Name			From - To (MM/YY – MM/YY)	
Essential Health solutions			05/14 - 09/18	
Business Address		**City**	**State**	**Zip**
1500 Sunday Drive, Suite 300		Raleigh	NC	27607
Phone	**Title**			
919-523-9914	Director			
Description of Duties				
Member of Board of Directors				

Continue on next page if additional space is needed.

Applicant's initials _____

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

SEE ATTACHMENT

Original Signature (electronic, copies or stamps not accepted)

5/15/23

Date

Applicant's Initials

Questions #4

STATEMENT AS TO DISCIPLINARY AND LEGAL ACTIONS OF PAST EMPLOYERS

It is in the context of having previously been affiliated with Accredo Health Group, Inc. and Medco Health Solutions, Inc. that I respond with a 'yes' to of your questions about whether they incurred disciplinary actions or were involved in litigation.

I was previously employed by Accredo Health Group, Inc. Accredo Health Group, Inc. was acquired by Medco Health Solutions, Inc., a Fortune 50 Company. Medco had one or more subsidiaries in the Medco Health Solutions, Inc. family of companies including Accredo Health, Inc. Medco Health Solutions, Inc. itself, together with one or more subsidiaries in the Medco Health Solutions, Inc. family of companies, owned and operated over 100 licensed pharmacies, holding in the aggregate hundreds of non-resident licenses, throughout the United States. Medco has since been acquired by Express Scripts.

I recall that commencing about 2003, Accredo Health Group, Inc. and certain of its officers and directors were named as defendants in several substantially similar putative class action lawsuits filed in the United States District Court. The lawsuits alleged violations of the Securities Exchange Act. In addition, two purported derivative lawsuits were filed in the Circuit Court. The lawsuits were resolved.

Also, from time to time, Medco and Accredo were involved in lawsuits, claims, audits and investigations arising in the normal course of their business. I recall in general that from time-to time, and over time, one or more of the pharmacies in the Medco family incurred disciplinary action inclusive of imposition of fines, for deficiencies or failures to comply with applicable pharmacy law. I do not recall any of these disciplinary actions with specificity, and do not know if any action resulted in suspension, revocation, or restriction of a pharmacy or other license.

I also recall in general that Medco from time-to time, and over time, closed one or more pharmacies for business reasons, voluntarily surrendering the pertinent license and DEA permit. I do not recall which locations voluntarily surrendered licenses or permits. I do not recall any involuntary license surrender or any license surrender while an action or investigation was pending or any surrender to avoid a further action.

I have a general recollection of Medco Health Solutions entering into a corporate integrity agreement with the federal government and another agreement with attorneys general, but do not recall any specifics.

Signed By: _____
Joel R. Kimbrough

Date: 5/15/23

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joel Kimbrough

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/15/23

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Joel R. Kimbrough, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/15/23

Date

Subscribed and Sworn to before me this 15 day of May.

Notary Public Signature

EMILY ERVIN
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

My Commission Expires March 11, 2026

(Seal)

Applicant's initials

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler AnovoRx Distribution, LLC

Physical Address 17500 South 40th St., Building B, Suite B600B

City Chandler State AZ Zip 85226

Mailing Address (if different from physical address) 1710 N Shelby Oaks Drive, Suite 2

City Memphis State TN Zip 38134

Telephone 901-201-5470 Website anovorx.com

Licensing Company Email Officialcontact@anovorx.com

Section 2: Personal Information

First Jonathan Middle Burrow Last Peters

Alias(es, nicknames, name changes, etc.) Jon

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Memphis State TN Zip 38117

Telephone 901-201-5470 Email Jon.Peters@anovorx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials JP

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		08/84 - 05/88	
Address	**City**	**State**	**Zip**
P.O. Box 1848	University	MS	38677
Diploma/Degree obtained, if any			
Bachelor Accountancy			

School Name		From - To (MM/YY – MM/YY)	
Memphis University School		08/80 - 05/84	
Address	**City**	**State**	**Zip**
6191 Park Avenue	Memphis	TN	38119
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2006 - Current	[redacted]	Memphis	TN	38117
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AnovoRx			08/12 - Present
Business Address	**City**	**State**	**Zip**
1710 N Shelby Oaks Drive, Suite 2	Memphis	TN	38134
Phone	**Title**		
901-201-5484	President/CEO		
Description of Duties			
Management of all company operations and activities			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Jon B. Peters

Applicant's initials _____

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This is in response to Question # 4,5,6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

See attached Statement of Disciplinary and other actions

Original Signature (electronic, copies or stamps not accepted)

05/11/2023
Date

Applicant's initials

Questions 4, 5, 6

STATEMENT AS TO DISCIPLINARY AND LEGAL ACTIONS OF PAST EMPLOYERS

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I have a general recollection of Medco Health Solutions entering into a corporate integrity agreement with the federal government and another agreement with attorneys general, but do not recall any specifics.

Signed By: Jon B Peters
Jon B. Peters

Date: 04/27/2023

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jon Peters

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/27/2023

Date

Please have this section completed in the presence of a Notary Public.

State of TN, ss. County of Shelby

I, Jon B. Peters, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/27/2023

Date

Subscribed and Sworn to before me this 27 day of April.

Notary Public Signature

EMILY ERVIN
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
My Commission Expires March 11, 2026

(Seal)

Applicant's initials

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: City Pharmacy 2

Physical Address: 6170 W Lake Mead Blvd

City: Las Vegas State: NV Zip: 89108

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7029121101 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 7029121598 Contact Email: professionalpharmacistlv@gmail.com

Website: www.citypharmacylv.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Muhammad Faisal Irshad Chaudhry

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19594

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Muhammad Faisal Irshad Chaudhry	NV Pharmacist Registration #: 19594
Name: Nureen Raza	NV Pharmacist Registration #: 15560
Name: Ali Raza	NV Pharmacist Registration #: 11705
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Professional Pharmacist LLC

Mailing Address: 11820 Glinda Ct

City: Las Vegas State: NV Zip: 89183

Telephone: 5164767482 Email: professionalpharmacistlv@gmail.com

Contact Person Name: Muhammad Faisal Irshad Chaudhry

Please check type of partnership (NAC 639.214) ☐ General ☒ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Pharmacist (title) for City Pharmacy 2 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Muhammad Faisal Irshad Chaudhry

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

01/23/2024

Date

GAUVIA GOODLEIGH
Notary Public
State of Nevada
Appt No 21-6808-01
My Appt Expires May 11, 2025

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Muhammad Faisal Irshad Chaudhry hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Pharmacist (title) for City Pharmacy 2 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 23RD day of JAN, 2024

Notary Public

GAUVIA GOODLEIGH
Notary Public
State of Nevada
Appt. No. 21-6808-01
My Appt. Expires May 11, 2025

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Muhammad Faisal Irshad Chaudhry Pharmacist Registration #: 19594

Pharmacy Name: City Pharmacy 2

Initial each statement below to indicate you have read and agree with the following:

X	I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
X	I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
X	I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
X	I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
X	I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

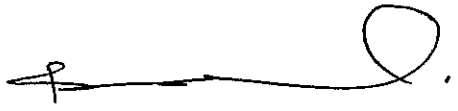
01/23/24
Date

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** o **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded -** The top 4 shareholder/stockholders. b. **For Partnerships -** All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	✓	✓	✓
• **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f)	✓	✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a)	✓	✓	✓	✓
• **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g)	✓	✓	✓	✓
• **Copy of DEA Registration if the pharmacy will be handling or dispensing controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)**	✓	✓	✓	✓
• **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)**	✓	✓	✓	✓
• **Transmit Controlled Substance Prescription Data-** Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Muhammad Faisal Irshad Chaudhry

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

01/23/2024

Date

Board Use Only	Date Received: _____ Amount: _____

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Professional Pharmacist LLC

Nevada Business Identification # NV20222552697
Expiration Date: 08/31/2023

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/25/2022.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate Number: B202208252953232
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, BARBARA K. CEGAVSKE, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Professional Pharmacist LLC** did, on 08/25/2022, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/25/2022.

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

Certificate
Number: B202208252953229
You may verify this certificate online at http://www.nvsos.gov

BARBARA K. CEGAVSKE
Secretary of State

KIMBERLEY PERONDI
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
202 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7138

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

08/25/2022

Work Order Item Number:	W2022082501713 - 2337784
Filing Number:	20222570982
Filing Type:	Initial List
Filing Date/Time:	08/25/2022 15:43:51 PM
Filing Page(s):	2

Indexed Entity Information:

Entity ID: E25709812022-7 **Entity Name:** Professional Pharmacist LLC

Entity Status: Active **Expiration Date:** None

Non-Commercial Registered Agent
Dionne Tsuneta
1105 S 8th St, Las Vegas, NV 89104, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division: The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

Barbara K. Cegavske

BARBARA K. CEGAVSKE
Secretary of State

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
Barbara K. Cegavske	E25709812022-7
Secretary of State	Filing Number 1670
State Of Nevada	20222570980
	Filed On
	08/25/2022 15:43:50 PM
	Number of Pages
	3

Formation - Limited-Liability Company

- [x] NRS 86 - Articles of Organization Limited-Liability Company
- [ ] NRS 86.544 - Registration of Foreign Limited-Liability Company
- [ ] NRS 89 - Articles of Organization Professional Limited-Liability Company
- [ ] NRS 86.555 - Registration of Professional Foreign Limited-Liability Company

1. Name Being Registered in Nevada: (See instructions)
Professional Pharmacist LLC

2. Foreign Entity Name: (Name in home jurisdiction)

3. Jurisdiction of Formation: (Foreign Limited-Liability Companies)
3a) Jurisdiction of formation:
3b) Date formed:
3c) I declare this entity is in good standing in the jurisdiction of its formation. [ ]

4. Registered Agent for Service of Process*: (check only one box)
[ ] Commercial Registered Agent (name only below) [x] Noncommercial Registered Agent (name and address below) [ ] Office or position with Entity (title and address below)

Dionne Tsuneta
Name of Registered Agent OR Title of Office or Position with Entity

1105 S 8th St | Las Vegas | Nevada | 89104
Street Address | City | Zip Code

Mailing Address (If different from street address) | City | Nevada | Zip Code

4a. Certificate of Acceptance of Appointment of Registered Agent:
I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.

X Dionne Tsuneta — Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity
08/25/2022 — Date

5. Management: (Domestic Limited-Liability Companies only)
Company shall be managed by: (check one box) [ ] Manager(s) OR [x] Member(s)

6. Name and Address of each Manager(s) or Managing Member(s): (NRS 86 and NRS 86.544, see instructions)
Name and Address of the Original Manager(s) and Member(s): (NRS 89, see instructions)
IMPORTANT:
A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing.

1) Muhammad Chaudhry
Name
11820 Glinda Ct | Las Vegas | NV | 89183
Address | City | State | Zip Code

2) Nureen Raza
Name
[redacted]Pale Pavilion Ave | Las Vegas | NV | 89139
Address | City | State | Zip Code

7. Dissolution Date: (Domestic only)
Latest date upon which the company is to dissolve (if existence is not perpetual):

This form must be accompanied by appropriate fees.

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Formation - Limited-Liability Company

Continued, Page 2

8. Profession to be Practiced: (NRS 89 only)

9. Series and/or Restricted Limited-Liability Company: (Optional)

Check box if a Series Limited-Liability Company ☑

Domestic Limited-Liability Company's only: The Limited-Liability Company is a Restricted Limited-Liability Company ☐

10. Records Office: (Foreign Limited-Liability Companies)

Address | City | State | Zip code

Country

11. Street Address of Principal Office: (Foreign Limited-Liability Companies)

Address | City | State | Zip code

Country

12. Name, Address and Signature of the Organizer: (NRS 86, NRS 89 - Each Organizer must be a licensed professional.)

Name and Signature of Manager or Member: (NRS 86.544 only)

See instructions

*Foreign Limited-Liability Company - In the event the designated Agent for Service of Process resigns and is not replaced or the agent's authority has been revoked or the agent cannot be found or served with exercise of reasonable diligence, then the Secretary of State is hereby appointed as the Agent for Service of Process.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

Muhammad Chaudhry — United States
Name — Country

11820 Glinda Ct — Las Vegas — NV — 89183
Address — City — State — Zip/Postal Code

X Muhammad Chaudhry (attach additional page if necessary)

Nureen Raza — United States
Name — Country

[redacted]Pale Pavilion Ave — Las Vegas — NV — 89139
Address — City — State — Zip/Postal Code

X Nureen Raza (attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Professional Pharmacist LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

- ☐ Corporation
  - ☐ This corporation is publicly traded, the Central Index Key number is:
- ☐ Nonprofit Corporation (see nonprofit sections below)
- ☑ Limited-Liability Company
- ☐ Limited Partnership
- ☐ Limited-Liability Partnership
- ☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)
- ☐ Business Trust

Filed in the Office of	Business Number
Barbara K. Cegavske	E25709812022-7
Secretary of State	Filing Number
State Of Nevada	20222570982
	Filed On
	08/25/2022 15:43:51 PM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

- ☐ 001 - Governmental Entity
- ☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

- ☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C § 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

- ☐ Unit-owners' Association
- ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. §501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

- ☐ No - no additional form is required
- ☐ Yes - the "Charitable Solicitation Registration Statement" is required.
- ☐ The Organization claims exemption pursuant to NRS 82A.210 - the "Exemption From Charitable Solicitation Registration Statement" is required

"Failure to include the required statement form will result in rejection of the filing and could result in late fees."

BARBARA K. CEGAVSKE
Secretary of State
202 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE MANAGING MEMBER:

Name	Country
Muhammad Chaudhry	USA

Address	City	State	Zip/Postal Code
11820 Glinda Ct	Las Vegas	NV	89183

CORPORATION, INDICATE THE MANAGING MEMBER:

Name	Country
Nureen Raza	USA

Address	City	State	Zip/Postal Code
[redacted]Pale Pavilion Ave	Las Vegas	NV	89139

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X Nureen Raza

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Title	Date
Managing Member	08/25/2022

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: CITY PHARMACY II

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 420 N. NELLIS BLVD SUITE A-1

City: LAS VEGAS State: NV Zip: 89110

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email: PROFESSIONALPHARMACISTLV@GMAIL.COM

Section 2: Personal Information

First: MUHAMMAD Middle: FAISAL Last: CHAUDHRY

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: LAS VEGAS State: NV Zip: 89183

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
UNIVERSITY OF THE PUNJAB	07/2007 to 01/2012

Address	City	State	Zip
THE MALL ROAD	LAHORE		54000

Diploma/Degree obtained, if any: PHARM D

School Name	From - To (MM/YY – MM/YY)
FC COLLEGE	09/2003 TO 09/2005

Address	City	State	Zip
CANAL ROAD	LAHORE		54600

Diploma/Degree obtained, if any: F.SC (FACULTY OF SCIENCES)

School Name	From - To (MM/YY – MM/YY)
THE PUNJAB SCHOOL	03/1994 TO 06/2003

Address	City	State	Zip
THE TOWNSHIP	LAHORE		54770

Diploma/Degree obtained, if any: SECONDARY SCHOOL CERTIFICATE

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2020 TO DATE	[redacted]	LAS VEGAS	NV	89183
01/2016 TO 07/2020	[redacted]	LAS VEGAS	NV	89102
10/2012 TO 01/2016	[redacted]	LAS VEGAS	NV	89139

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CITY PHARMACY			04/2017 TO DATE
Business Address	**City**	**State**	**Zip**
1131 E. TROPICANA AVE STE A-1	LAS VEGAS	NV	89119
Phone	**Title**		
702-816-4277	STAFF PHARMACIST		
Description of Duties			
MANAGE PHARMACYDAY TO OPERATION. DISPENSING PRESCRIPTIONS			

Business Name			From - To (MM/YY – MM/YY)
FAMILY PHARMACY			10/2015 TO 08/2016
Business Address	**City**	**State**	**Zip**
4527 W. SAHARA AVE	LAS VEGAS	NV	89102
Phone	**Title**		
702-413-6500	INTERN PHARMACIST		
Description of Duties			
PHARMACY OPERATION UNDER THE SUPERVISION OF A PHARMACIST DISPENSING PRESCRIPTIONS			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/26/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Muhammad F Chaudhry

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/12/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of CLARK

I, Muhammad F Chaudhry, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/12/24

Date

Subscribed and Sworn to before me this 12th day of FEBRUARY 2024.

Notary Public Signature

RAMESH CHANDRA PIPLANI
Notary Public, State of Nevada
No. 03-84825-1
My Appt. Exp. Oct. 15, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: CITY PHARMACY II

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 420 N. NELLIS BLVD SUITE A-1

City: LAS VEGAS State: NV Zip: 89110

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email: PROFESSIONALPHARMACISTLV@GMAIL.COM

Section 2: Personal Information

First: NUREEN Middle: Last: RAZA

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: LAS VEGAS State: NV Zip: 89139

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
B.Z. UNIVERSITY			12/1984 to 04/1991
Address	**City**	**State**	**Zip**
BOSIN ROAD	MULTAN		60000
Diploma/Degree obtained, if any			
B. PHARMACY			

School Name			From - To (MM/YY – MM/YY)
GOVT GIRLS COLLEGE			09/1982 TO 06/1984
Address	**City**	**State**	**Zip**
UNIVERSITY ROAD	BAHAWALPUR		631000
Diploma/Degree obtained, if any			
F.SC (FACULTY OF SCIENCES)			

School Name			From - To (MM/YY – MM/YY)
GOVT GIRLS HIGH SCHOOL			11/1980 TO 06/1982
Address	**City**	**State**	**Zip**
CHOWBARA ROAD	LAYYAH		
Diploma/Degree obtained, if any			
SECONDARY SCHOOL CERTIFICATE			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2005 TO DATE	[redacted]	LAS VEGAS	NV	89139

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
CITY PHARMACY			04/2017 TO DATE
Business Address	**City**	**State**	**Zip**
1131 E. TROPICANA AVE STE A-1	LAS VEGAS	NV	89119
Phone	**Title**		
702-816-4277	MANAGING PHARMACIST		
Description of Duties			
MANAGE PHARMACY OPERATION. DISPENSING PRESCRIPTIONS			

Business Name			From - To (MM/YY – MM/YY)
FAMILY PHARMACY			10/2013 TO 08/2016
Business Address	**City**	**State**	**Zip**
4527 W. SAHARA AVE	LAS VEGAS	NV	89102
Phone	**Title**		
702-413-6500	MANAGING PHARMACIST		
Description of Duties			
MANAGE PHARMACY OPERATION. DISPENSING PRESCRIPTIONS			

Business Name			From - To (MM/YY – MM/YY)
FAMILY PHARMACY			08/2010 TO 10/2013
Business Address	**City**	**State**	**Zip**
1360 E. HIGHWAY 372	PAHRUMP	NV	89048
Phone	**Title**		
775-751-1144	PHARMACIST		
Description of Duties			
DISPENSING PRESCRIPTION MANAGE DAY TO DAY BUSINESS OF PHARMACY AND INVETORY CONTROL INCLUDING PURCHASES.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/26/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

NUREEN RAZA

Print Name (First, Last)

Nureen.

Original Signature (electronic, copies or stamps not accepted)

2/12/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of CLARK

I, NUREEN RAZA, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nureen.

Original Signature

2/12/24

Date

Subscribed and Sworn to before me this 12th day of February 2024

Ramesh Piplani

Notary Public Signature

RAMESH CHANDRA PIPLANI
Notary Public, State of Nevada
No. 03-84825-1
My Appt. Exp. Oct. 15, 2024

(Seal)

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☑ Hospital (# beds 11)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☑ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☑ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☑ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER at Cadence (an extension of Henderson Hospital)

Physical Address: 865 E. Lake Mead Pkwy.

City: Henderson State: NV Zip: 89015

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: N/A Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: N/A

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Vincent Pham

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19646

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Vincent Pham (PIC)	NV Pharmacist Registration #: 19646
Name: Brian T. Cruz	NV Pharmacist Registration #: 16445
Name: Stephanie Nasti	NV Pharmacist Registration #: 16437
Name: Genevieve Zane	NV Pharmacist Registration #: 19765
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Universal Health Services

Corporation Name: Valley Health System LLC

Mailing Address: 67 South Gulph Road

City: King of Prussia State: PA Zip: 19406-0958

Telephone: 610-768-3300 Email: uhscorpfillings@uhsinc.com

Contact Person Name: Steve Filton

Date of SEC Registration: 1981 | SEC Registration Number: 1-10765 | Stock Exchange Symbol: UHS

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

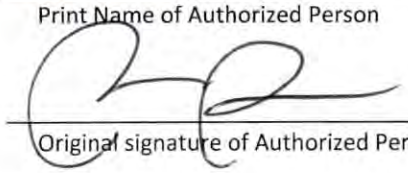
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Pharmacist (title) for ER at Cadence (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Vincent Pham

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

12/18/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Vincent Pham hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for ER at Cadence (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of December, 2023

Notary Public

ROBB PAPAGNO
Notary Public, State of Nevada
Appointment No. 16-2212-1
My Appt. Expires Apr 8, 2024

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Vincent Pham Pharmacist Registration #: 19646

Pharmacy Name: ER at Cadence

Initial each statement below to indicate you have read and agree with the following:

VP I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

VP I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

VP I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

VP I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

VP I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/18/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vincent Pham

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/18/23

Date

Board Use Only	Date Received: 12/20/23	Amount: $500 CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: ER at Cadence (an extension of Henderson Hospital)

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 865 E. Lake Mead Pkwy.

City: Henderson State: NV Zip: 89015

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: N/A Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: N/A Contact Email: N/A

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Vincent Pham

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19646

Name of Person with direct knowledge of compounding procedures: Brian Cruz

Email of Person with direct knowledge of compounding procedures: brian.cruz@uhsinc.com

Telephone of Person with direct knowledge of compounding procedures: 702-963-7190

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
We use Vial2Bag connectors for for most IVPB. Once assembled, IVPB are for immediate use only.

Due to storage limitations, we Add-A-Vial the following IVPB in the main pharmacy:
Amiodarone/D5W 450 mg/250 mL, Diltiazem/D5W 125 mg/125 mL, Sodium Phosphate/NS 15 mmol/100 mL, Phenylephrine/D5W 100 mg/250 mL, Nicardipine/NS 25 mg/250 mL, Furosemide/NS 100 mg/100 mL, Vancomycin/D5W 1.5 gm/500 mL, Vancomycin/D5W 1.75 gm/500 mL, Vancomycin /D5W 2 gm/500 mL, Pantoprazole/NS 40 mg/50 mL.

Nursing staff will only have to compound the following IVPB for immediate use. There is no clean room on site.
Crofab
Alteplase (PE)
Tenecteplase (Stroke)
Norepinephrine
Epinephrine

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visually inspected at the completion of compounding using black and white box. Visual inspection is again performed using black and white box prior to dispensing or loading in the Pyxis.

8. How often do you perform glove fingertip and medial fill testing?
Biannual for Henderson Hospital IV room technicain staff. Annual for all pharmacist at Henderson Hospital.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
The 3 successful completions must be in succession. Failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row (UHS Sterile Compounding SOP). IV Technician will not be allowed to work in IV while evauation is on going.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial media fill and gloved fingertip/thumb sampling. Biannual media fill and gloved fingertip/thumb sampling for IV room technicain staff. Annual media fill and gloved fingertip/thumb sampling for pharmacist staff.
Annual observation (with trainer): Donning of sterile gloves, hand hygiene and proper use of PPE.
Written Exam: NICU calculations, sterile compounding pharmaceutical calculations exam,
Cleaning/disinfecting/decontaming and cleaning,
Onsite training: Cleaning and proper use of cleaning supplies/materials (CONTEC).

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Contec Sterile Peridox RTU, Contec Sterile TB1-3300 Disinfectant, Contec Sterile 70% Isopropyl Alcohol.

Cleaning is performed immedately before compounding, if compounding activities takes longer than 30 minutes, at the end of each shift (twice daily), weekly and monthly (terminal clean).

12. Who performs the sterile compounding process at your facility?
IV room pharmacy technician staff. Compounding is done in the main hospital whenever possible (Henderson Hospital)

13. Who is responsible and accountable for the sterile compounding process at your facility?
Director of Pharmacy (Henderson Hospital).

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
N/A

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding:)		
1. What type of primary engineering controls will you be using in your facility? No sterile compounding room on site. All sterile compounding will be performed at Henderson Hospital outside of immediate use CSPs.		
2. Is your BSC or CACI vented 100% to the outside?	☒ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☒ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☒ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☒ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☒ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Initial media fill and gloved fingertip/thumb sampling. Biannual media fill and gloved fingertip/thumb sampling for IV room technicain staff. Annual media fill and gloved fingertip/thumb sampling for pharmacist staff. Observation (with trainer): HD hand hygiene and garbing, HD sterile compounding/aseptic technique + Chemo Test, HD sterile compounding environment/deactivation/decontamination and cleaning, donning of sterile gloves. Written examination: USP 800 PPE, USP 800 proper use of equipment, USP 800 spill management, USP 800 Sterile compounding and USP 800 general exam. Onsite training: Closed system devices (Baxter).		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
N/A

2. What sterilization methods are utilized at your facility?
N/A

3. Does your facility utilize biological indicators? ☐ Yes ■ No

4. If yes, describe how they are utilized:
N/A

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Cruz
Name of Person who Completed the Form

Director of Pharmacy
Title

Signature (copies or stamps not accepted)

12/5/23
Date

Board Use Only	Date Received: 12/20/23 Date Approved: _____ Approved By: _____

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

VALLEY HEALTH SYSTEM LLC

Nevada Business Identification # NV19981003340
Expiration Date: 01/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/09/2023.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202301093294239
You may verify this certificate online at http://www.nvsos.gov

- List all Officers and Directors: NRS 639.231(2)(b), NAC 639.214(5)(a)
  - Edward Sim – President (Director)
  - Steve Filton – Vice President (Director)
  - Matthew Klein – Vice President, Secretary (Director)
  - George H. Brunner, Jr. – Assistant Secretary
  - Cheryl K. Ramagano – Treasurer
  - Robert Zurad – Assistant Treasurer

- **List the top four stockholders and their percent ownership. NRS 639.231(3)**

  For UHS, Inc.: Alan B. Miller – 11.9%; The Vanguard Group – 11.5%; FMR LLC – 8.1%; BlackRock, Inc. – 7.3%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VALLEY HEALTH SYSTEM LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VALLEY HEALTH SYSTEM LLC" WAS FORMED ON THE SIXTEENTH DAY OF JANUARY, A.D. 1998.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2847793 8300

SR# 20233236298

Authentication: 203953874

Date: 08-14-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☒ Hospital (# beds 12) ☐ Internet ☐ Nuclear ☒ Other: Free standing ER department of Southern Hills Hospital	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☒ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER at Desert's Edge

Physical Address: 9075 Blue Diamond Road

City: Las Vegas State: NV Zip: 89178

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: NamDavid.Nguyen@healthtrustpg.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Reggie Maynigo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 16169

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Nam Nguyen	NV Pharmacist Registration #: 19048
Name: Reggie Maynigo	NV Pharmacist Registration #: 16169
Name: Deborah Liechty	NV Pharmacist Registration #: 23826
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): HCA Healthcare

Corporation Name: HCA Healthcare Inc.

Mailing Address: One Park Plaza

City: Nashville State: TN Zip: 37203

Telephone: 615-344-9551 Email:

Contact Person Name: Alexis Mussi, CEO Southern Hills Hospital

Date of SEC Registration: September 1993 | SEC Registration Number: 333-145054 | Stock Exchange Symbol: HCA

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Pharmacy (title) for ER at Desert's Edge (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Nam Nguyen

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/17/24

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Reggie Maynigo Pharmacist Registration #: 16169

Pharmacy Name: ER at Desert's Edge

Initial each statement below to indicate you have read and agree with the following:

h	I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
h	I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
h	I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
h	I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
h	I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

1/17/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexis Mussi

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Alexis Mussi

Original signature of Authorized Person (copies or stamps not accepted)

1/17/24

Date

Board Use Only	Date Received: 1/22/24	Amount: $500-cc

SOUTHERN HILLS.
HOSPITAL & MEDICAL CENTER

Applicant: ER at Desert's Edge

HCA Healthcare Officers

Title	Name
Chief Executive Officer	Samuel Hazen
Chief Financial Officer	William Rutherford
Chief Operating Officer	Jon Foster
Chief Clinical Officer	Michael Cuffe
Chief Human Resources Officer	Jennifer Berres
Chief Legal Officer	Michael McAlevey
Chief Information Officer	P. Martin Paslick
Chief Ethics & Compliance Officer	Kathi Whalen

Southern Hills Hospital & Medical Center Officers

Title	Name
Chief Executive Officer	Alexis Mussi
Chief Financial Officer	Sonia Baughman
Chief Operating Officer	Jason Desai
Chief Nursing Officer	Blake Romero

Applicant: ER at Desert's Edge

HCA Healthcare Top 4 Stockholders

Stockholder	Percent Ownership
Vanguard Group, Inc	6.4%
Blackrock, Inc	5.69%
Sanders Capital, LLC	4.09%
Wellington Management Group, LLP	3.74%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **SOUTHERN HILLS MEDICAL CENTER, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/14/2002, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/08/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202401084251290
You may verify this certificate online at http://www.nvsos.gov

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FW3475402
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH. 02855		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: OK'CARE PHARMACY

Physical Address: 4845 SOUTH RAINBOW BLVD, SUITE 403

City: LAS VEGAS State: NEVADA Zip: 89103

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7025389388 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 7027768982 Contact Email: ikeokoye@okcarepharmacy.com

Website: stores.healthmart.com

Nevada Business License # (if applicable) NV20121177058

Supervising/Managing Pharmacist Name (NRS 639.220): IRIS KHUMALO-MUSAH

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19747

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: IRIS KHUMALO-MUSAH	NV Pharmacist Registration #: 19747
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: AHUNNA OKOYE

Business Name: W CARE LLC dba OK'CARE PHARMACY

Business Address: 4845 SOUTH RAINBOW BLVD, SUITE 403

City: LAS VEGAS State: NEVADA Zip: 89103

Telephone: 702 538 9388 Email: iykeokoye@wcarepharmacy.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the OWNER/PHARMACIST (title) for OKCARE PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

ANUNA CHIJIOKE OKOYE

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/6/23

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: IRIS KHUMALO-MUSAH Pharmacist Registration #: 19747

Pharmacy Name: OK CARE PHARMACY

Initial each statement below to indicate you have read and agree with the following:

I.K I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I.K I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I.K I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I.K I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I.K I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/6/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ATHANNA CHITURU OKOYE

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Okoye

Original signature of Authorized Person (copies or stamps not accepted)

12/6/23

Date

Board Use Only	Date Received: 12/12/23	Amount: $500-check 2314

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

W CARE LLC

Nevada Business Identification # NV20121177058
Expiration Date: 03/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/09/2023.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202301093296106
You may verify this certificate online at http://www.nvsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site OK CARE PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PHC02855

Physical Address 4845 SOUTH RAINBOW BLVD, SUITE 403

City LAS VEGAS State NEVADA Zip 89103

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7025389388 Website stores.healthmart.com

Licensing Company Email iykeokoye@okcarepharmacy.com

Section 2: Personal Information

First ANNA Middle CHIGURU Last OKOYE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted] Huxley Cass LANE

City Las Vegas State NV. Zip 89144

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)
University of Florida		01/2011 – 12/2013
Address	**City**	**State / Zip**
1225 Center Drive	Gainesville	FL 32610
Diploma/Degree obtained, if any		
Doctor of Pharmacy (PharmD)		

School Name		From - To (MM/YY – MM/YY)
University of Nigeria		09/84 – 10/89
Address	**City**	**State / Zip**
Obukpa Road	Nsukka	Enugu 410001
Diploma/Degree obtained, if any		
Bachelors of Pharmacy (BPharm)		

School Name		From - To (MM/YY – MM/YY)
Federal Government Girls College		09/78 – 07/83
Address	**City**	**State / Zip**
General hospital Rd, Vandeikeya highway	Gboko	Benue 981101
Diploma/Degree obtained, if any		
West African Examination council certificate		

School Name		From - To (MM/YY – MM/YY)
Address	**City**	**State / Zip**
Diploma/Degree obtained, if any		

School Name		From - To (MM/YY – MM/YY
Address	**City**	**State / Zip**
Diploma/Degree obtained, if any		

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Oct. 1998 – Date	[redacted] Lane Huxley Cross	Las Vegas	NV	89144
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Summerlin Hospital			From - To (MM/YY – MM/YY): 10/98 – Date
Business Address: 657 Town Center drive	City: Las Vegas	State: NV.	Zip: 89144
Phone: 702 233 7380	Title: Clinical Staff Pharmacist		
Description of Duties: Evaluate, interpret, compound and dispense medications according to orders issued by authorized prescribers. Promote thorough criteria based protocols, clinically rational drug therapy and care. Participate in study drug trials and more			

Business Name: Okcare Pharmacy			From - To (MM/YY – MM/YY): 04/2012 – Date
Business Address: 4845 S. Rainbow Blvd, Ste #403	City: Las Vegas	State: NV	Zip: 89103
Phone: (702) 538 9388	Title: Pharmacist Owner		
Description of Duties: Dispense patient medications/prescriptions. Prioritize patient well being by offering comprehensive medication counseling, addressing medication related concerns, and resolving issues promptly and more.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AHUNNA OKOYE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/6/23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, AHUNNA OKOYE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/6/23

Date

Subscribed and Sworn to before me this 6TH day of DECEMBER.

Notary Public Signature

JAMES RYAN HART
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 12-18-2023
Certificate No: 12-8809-1

(Seal)

W-Care LLC, dba OK-Care Pharmacy
Transfer and Consolidation of Members Interest in Company

On March 18, 2012, W-Care, LLC was organized and registered with the Nevada Secretary of State. John I. Okoye and Ahunna C. Okoye were both designated as Managing Members of W-Care, LLC on the initial list.

John I. Okoye was an Initial Member of W-Care, LLC with an initial ownership interest in W-Care, LLC of ninety percent (90%). Ahunna C. Okoye was the only other Initial Member of W-Care, LLC with an initial ownership interest in W-Care, LLC of ten percent (10%).

On July 4, 2022, John I. Okoye died in the City of Las Vegas, Clark County, Nevada. As a result, Ahunna C. Okoye is the sole Member and Managing Member.

In accordance with the authority reserved to the Initial Members under Article Five, Section 5.03(c) of the Operating Agreement of W-Care, LLC, Ahunna C. Okoye hereby consolidates and transfers all John I. Okoye's Membership Interests in W-Care, LLC to Ahunna C. Okoye. As a result, Ahunna C. Okoye now holds one hundred percent (100%) of the Ownership Interests in W-Care, LLC.

In accordance with the Operating Agreement of W-Care, LLC, Article Four, Section 4.03, a single Member, regardless of the Member's percentage of Ownership Interest, has the right to approve the sale of all of the Company's assets as part of a single transaction.

MEMBER, W-CARE, LLC.

Okoye 3/1/23

By: AHUNNA C. OKOYE DATE

STATE OF NEVADA)
) ss
COUNTY OF CLARK)

On this 1 day of March, 2023, before me, Taylor Hix personally appeared AHUNNA C. OKOYE, personally known to me, or proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the foregoing TRANSFER AND CONSOLIDATION OF MEMBERS INTEREST IN COMPANY, and acknowledged to me that she executed the same in her authorized capacity, and that by her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

WITNESS my hand and official seal
this 1 day of March, 2023.

TAYLOR HIX
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 21-9750-01
MY APPT. EXPIRES DECEMBER 04, 2024

NOTARY PUBLIC in and for
said County and State

Notary Seal

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ahunna Okoye hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner / Pharmacist (title) for Ok'care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 6TH day of DECEMBER, 2023

Notary Public

JAMES RYAN HART
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 12-18-2023
Certificate No: 12-8809-1

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☒ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Apothecary Options

Physical Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 530-345-7979 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 530-345-9797 Contact Email: danny@apothecaryoptions.com

Website: www.apothecaryoptions.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Danny Abifadel

Supervising/Managing Pharmacist NV Pharmacist Registration #: 56613 (CA) 24030 -NV

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: n/a	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): n/a

Corporation/Organization Name: Apothecary Options, Inc.

Mailing Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Telephone: 530-345-7979 Email: danny@apothecaryoptions.com

Contact Person Name: Danny Abifadel

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility- MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner/PIC (title) for Apothecary Options (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Danny Abifadel

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

03/16/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Danny Abifadel hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner/PIC (title) for Apothecary Options (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

Notary Public

See attached
OA Jurat

CALIFORNIA JURAT WITH AFFIANT STATEMENT GOVERNMENT CODE § 8202

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Butte

ANGELA C. COOK
COMM. # 2412056
NOTARY PUBLIC · CALIFORNIA
COUNTY OF BUTTE
Comm. Expires AUG. 28, 2026

Place Notary Seal and/or Stamp Above

Subscribed and sworn to (or affirmed) before me
on this 31st day of March, 2023
by *Date* *Month* *Year*
(1) Danny Nabil Albifadel
(and (2) _____),
Name(s) of Signer(s)
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Affidavit for Pharm. License

Document Date: _____ Number of Pages: _____

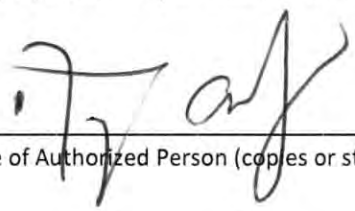
Signer(s) Other Than Named Above: _____

©2017 National Notary Association

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Danny Abifadel

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

03/16/2023

Date

Board Use Only	Date Received: 4-17-23	Amount: 500.00 CK-1020

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	APOTHECARY OPTIONS, INC.
Entity No.:	2353631
Registration Date:	08/03/2001
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 01, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 104670621

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

BA20230477020

STATE OF CALIFORNIA
Office of the Secretary of State
STATEMENT OF INFORMATION
CORPORATION

California Secretary of State
1500 11th Street
Sacramento, California 95814
(916) 653-3516

For Office Use Only

-FILED-

File No.: BA20230477020
Date Filed: 3/21/2023

Entity Details

Corporation Name	APOTHECARY OPTIONS, INC.
Entity No.	2353631
Formed In	CALIFORNIA

Street Address of Principal Office of Corporation

Principal Address	3006 ESPLANADE, STE I I CHICO, CA 95973

Mailing Address of Corporation

Mailing Address	3006 ESPLANADE STE I I CHICO, CA 95973
Attention	Danny Abifadel

Street Address of California Office of Corporation

Street Address of California Office	3006 ESPLANADE, STE I I CHICO, CA 95973

Officers

Officer Name	Officer Address	Position(s)
DANNY N ABIFADEL	3006 ESPLANADE STE I CHICO, CA 95973	Chief Executive Officer, Chief Financial Officer, Secretary

Additional Officers

Officer Name	Officer Address	Position	Stated Position
None Entered			

Directors

Director Name	Director Address
Danny Abifadel	3006 ESPLANADE I CHICO, CA 95973

The number of vacancies on Board of Directors is: 0

Agent for Service of Process

Agent Name	DANNY N ABIFADEL
Agent Address	3006 ESPLANADE STE I CHICO, CA 95973

Type of Business

Type of Business	PHARMACY

Email Notifications

Opt-in Email Notifications	Yes, I opt-in to receive entity notifications via email.

Labor Judgment

B1604-6835 03/21/2023 8:59 AM Received by California Secretary of State

No Officer or Director of this Corporation has an outstanding final judgment issued by the Division of Labor Standards Enforcement or a court of law, for which no appeal therefrom is pending, for the violation of any wage order or provision of the Labor Code.

Electronic Signature

☒ By signing, I affirm that the information herein is true and correct and that I am authorized by California law to sign.

danny abifadel
Signature

03/21/2023
Date

B1604-6836 03/21/2023 8:59 AM Received by California Secretary of State

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

1740

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA9089916	06-30-2025	$888

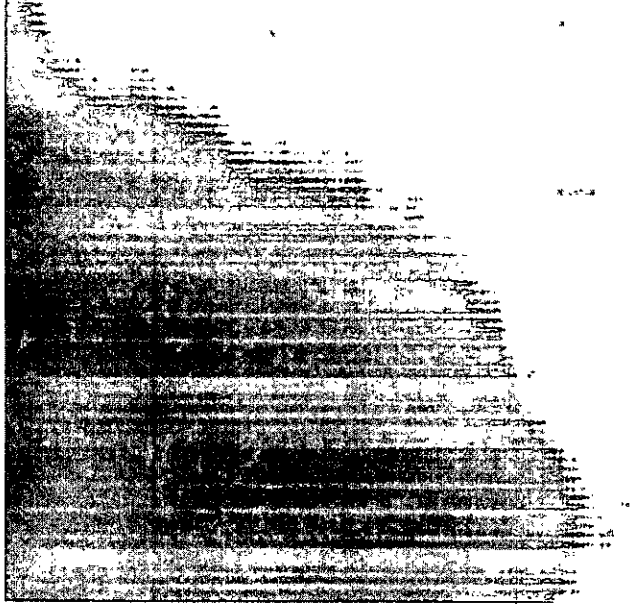
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	05-13-2022

APOTHECARY OPTIONS
3006 ESPLANADE STE I
CHICO, CA 95973-0285

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)



STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO. PHY 57642 ISSUE DATE FEBRUARY 24, 2020

APOTHECARY OPTIONS

3006 ESPLANADE STE I
CHICO CA 95973

The above is licensed with the State Board of Pharmacy as a Corporation.

CORPORATION
DANNY NABIL ABIFADEL PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

FORM WPHPHY (09/30/19) PH

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

VALID UNTIL FEBRUARY 01, 2024

LICENSE NO. PHY 57642
RECEIPT NO. 23330245

APOTHECARY OPTIONS
3006 ESPLANADE STE I
CHICO CA 95973

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

12/01/22
12/01/22

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 4/5/2022 Inspector: Mojgan Mohammadzadeh

Firm: APOTHECARY OPTIONS Phone: (908) 991-6979

Address: 3006 ESPLANADE STE I City: CHICO Zip: 95973

Ownership: CORPORATION

Permit #: PHY57642 Permit Exp: 2/1/2023 DEA#: FA9089916 DEA Exp: 6/30/2022

Date of Self Assessment Form: 3/18/2021 Other Permit #: N/A Date of DEA Inventory: 3/15/2022

Hours M-F: 8:30-5:30 Hours Saturday CLOSED Hours Sunday: CLOSED

PIC DANNY N ABIFADEL RPH56613 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
		HANNAH MOORE	CLERK
		JACQUELINE	CLERK
		RANDAL E SMITH	TCH3833

Inspector Remarks:

Routine inspection assisted by
Description of pharmacy:
This is a new retail compounding pharmacy opened in February 2020, non-sterile only & HD
Servicing to individual patients and a local Hospice
Averaging 50-60 compounds daily, 40-50% HD
Compounding Pharmacy Self-Assessment.
Wholesaler: Medisca, Letco, Fagron and PCCA
Consultation: Observed at time of inspection, MAIL (delivery) consultation
Services provided include compounding, mailed prescriptions, ships refrigerated items (1-2 a years)

Reviewed:
Notices to the public: Pharmacy permit and renewal; DEA registration; Notice to Consumer Poster; Language notice
ID Badges, Ratio, Staff licensing, Pharmacy and Licensee emails registered with the board

Biennial inv 3/15/22 closing, 222 date/qty rec, DEA 106 (none) , CII invoice & RX separate , CII Reconciliation 12/15/22 through 3/15/22, CS daily printout, CII (CSOS DEA 222) and CIII-V invoices; CURES data submitted daily via PMP Bamboo

Security, Keys, Sink (hot/cold) H2O, Clean/orderly, Stock/Refrigerator (36F-46F)(2-8c) (manual logged daily),Restroom cleanliness, Pharmacological References: Lexicomp (LexiDrug)

Spot check of active stock for expired drugs; Drug acquisition and disposition procedures; Recalls, outdates, and hazardous waste quarantined and properly labelled; Sample of recent prescriptions in will call, PSE none in stock
Records storage withing the pharmacy

Policies and Procedures: Impaired employee/Theft and diversion; Technician Job Description; Interpretive service provided by scientific language.
Reviewed annually by PIC date and signed, Staff notified of change, recall plan, Equipment cleaning and calibration prior to use: P&P's match practice, Quality Assurance for End product testing on 12/3/21 by ARL with Ivermectin, BUD methodology, Storage of compounds with Room Temp, refrigerator Temp and freezer Temp and appropriate functioning of them and out of range actions, Quality Assurance Program for Med error (none)
Reverse distributor: sharps Complaint; **Hazardous waste removal:** NRC environmental services

Master formula/BUD methodology/compounding logs
Cleaning and disinfecting compounding area
Ongoing training of staff
Equipment maintenance, calibration prior to use, cleaning
Protective clothing
Temperature studies for shipped compounded products- 1-2 RX a year with WarmMark thermostat
Drug storage * temp monitoring in room, refrigerator and freezer

Dispensing process; Sample of recent CII and CIII-V prescriptions; Patient centered labels, RPh initials, intake & disp. RPh identified, Opioid warning.

Will call area: Return to stock procedures; random prescription check
Compounding area:
HD compounding room access is through non-HD compounding room
& None compounding rooms have PEC certified by CERT last on 2/9/22
drugs are stored in HD room and none HD drugs are stored within non-HD compounding room
are stored on shelves outside compounding room
TCH Scott demonstrated garbing for HD room as gown first, then double shoe cover, mask, hairnet and double gloves. Second pair of glove was made by TechNitrile
Decontamination/Inactivation for HD: Daily: Preempt RTU, 70% IPA and Q3months: Peridox RTU +70% IPA

Labeling requirements: Pharmacy lot number, compounded by pharmacy, Generic names of principal ingredients, Date compounded, BUD and instruction for storage, Rate and route

Education provided:
1. Transmission of controlled substance prescriptions of CII,III,IV and V to CURES: not more than one working day after the date a controlled substance prescription is released to the patient/patient's representative. *HSC 11165*
2. Duty to consult: if prescriptions shipped by mail or delivered by pharmacy, the patient must receive written notice of rights to consultation; hours of availability, telephone number for consultation; pharmacist available during regular hours of operation, within 10 minutes or less or a return call within one business hour, no less than 6 days/week for minimum of 40hours/week. *CCR1707.2*
3. Community pharmacy/Hospital Outpatient Self-Assessment 17M-13 Rev.1/2021 available on-board website.
4. Drug take-back receptacles require registration with DEA and notification to the board within 30 days. To notify the board: http://www.pharmacy.ca.gov/licensees/drug_takeback.shtml. To look up drug take-back locations: https://www.pharmacy.ca.gov/consumers/drug_takeback.shtml. *CCR1776.1*
5. Pharmacist license renewal requirement: at least two of the 30 hours of required continuing education must be completed by participation in a Board-provided CE course in Law and Ethics. Available on Board's website: http://www.pharmacy.ca.gov/licensees/webinars/law_ethics.shtml.
6. **September 2021 SCRIPT Newsletter** now available on the Board's website at www.pharmacy.ca.gov

ussion:

- Record Keeping – maintain for 3 years (1735.2 (d) (e)
- Negative pressure monitor is located in far corner of the compounding room hidden behind equipment and

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Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

difficult to view correct reading. Consider moving its location.

- Math test given to TCH Scott was identical to year before
- Expired CS quarantined in the same tote as non-CS medication
- Picked up 4 RX label, compounding log and copy of original. Receipt #830025 was issued with prescription numbers noted

Email **proof of correction** for all items on the **Order of Correction** to Inspector Mojgan Mohammadzadeh, using the EMAIL information listed below, by close of business, 5pm on Tuesday, 4/19/22

Mojgan Mohammadzadeh
Inspector, CA Board of Pharmacy
2720 Gateway Oaks Drive
Sacramento, CA 95833
Phone: 916-531-6246
Email: mojgan.mohammadzadeh@dca.ca.gov

For questions pertaining to pharmacy law, please contact the board Monday through Thursday from 9am to 1pm.
Email: ask.inspector@dca.ca.gov (Include name, organization, phone, and best call time)
Fax: (916) 574-8618
Phone: (916) 518-3100

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____
Pharmacist (print) Dawn Abitadel

Inspector (sign) _____
Inspector (print) Mojgan M.Zadeh

Owner(sign) _____
Owner(print) Dawn Abitadel

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

1745

ORDER OF CORRECTION

Date: 4/5/2022 Permit #: PHY57642

Time of Day: 12:38 PM

Name as shown on permit: **APOTHECARY OPTIONS**

Address: 3006 ESPLANADE STE I City: CHICO

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1.	**CCR 1735.4**	Labeling of Compounded Drug Preparations. In that at the time of inspection labels RX#106803, 107252, 109278, 109271 did not have "the date compounded". Please send proof of correction.
2.	**CCR 1714(b)**	Operational Standards and Security. Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. In that at the time of inspection the small brown patient refrigerator had frost build up. Please defrost and send me a picture.
3.	**BPC 4104(c)(1)**	Licensed Employee, Theft or Impairment: Pharmacy Procedures. Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof the following information with regard to any licensed individual employed by or with the pharmacy: Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice. In that at the time of inspection, PIC Abifadel could not locate pnp in line with Board's requirement. Please send me a copy of Theft or Impaiment PnP.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) _____ Print Name Danny Abifadel

Date 4/5/22 Title Owner

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

California State Board of Pharmacy
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Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

OFFICIAL RECEIPT

April 05, 2022 .

Receipt Number: 830025

Firm: APOTHECARY OPTIONS

Address: 3006 ESPLANADE STE I, CHICO CA 95973

Permit #: PHY57642

Phone: (908) 991-6979

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Qty	Units	Description
8	Ea	picked up a copy oforiginal RX#109278, 107252,106803,109271 along with its corresponding compounding log and label

Voluntarily Released for Investigation

Receipt acknowledged by: _____ Title

Inspector: _____

Danny

From: Danny
Sent: Wednesday, April 6, 2022 7:01 AM
To: 'mojgan.mohammadzadeh@dca.ca.gov'
Subject: Apothecary Options Order of Corrections
Attachments: 8.010-Code of Conduct, impairment, theft.docx; Patient Fridge.jpg; Compounded on date Rx label.png

Good Morning Mojgan~

Thank you for visiting our Pharmacy yesterday and appreciate all the information. Please find below the order of corrections for the 3 findings. I hope they meet your satisfaction.

1. Ccr 1735.4- Attached is the new label that has the "compounded date" on the label as requested.
2. CCR 1714- Attached is a photo of the de-iced patient will call fridge
3. BPC 4104- Attached is a copy of the revised PnP which now includes the verbiage for Theft and Impairment. You will find it under Section 9.5 of the Policy.

Please let me know if there is anything else you need.

Thanks and have a wonderful day,

Danny

Dr. Danny Abifadel
Pharmacist/Owner
Apothecary Options

Danny

From: Danny
Sent: Thursday, April 7, 2022 4:48 PM
To: Mohammadzadeh, Mojgan@DCA
Subject: Re: Apothecary Options Order of Corrections

Hello-
Please see attached.

Danny Abifadel, Pharm.D
President/Owner
Apothecary Options, Inc.
P.530-345-RxRx (7979)
F.530-345-9797
C.530-774-3174
apothecaryoptions.com

On Apr 7, 2022, at 16:41, Mohammadzadeh, Mojgan@DCA <Mojgan.Mohammadzadeh@dca.ca.gov> wrote:

Danny,
Please send me a picture of your Hood inside the HD room so I can see that is externally vented.

Thank you

Mojgan Mohammadzadeh, Pharm.D., Inspector
(pronouns: she,her,hers)
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento,Ca.95833
(916) 531-6246 | FAX (916) 574-8618 |
Mojgan.mohammadzadeh@dca.ca.gov
www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!

In the event you received it in error, please contact the sender and destroy all copies of the original message.

Useful links:
2022 law book: **http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf**

For the most updated BOP COVID-19 waivers:
https://pharmacy.ca.gov/licensees/emergency_declaration.shtml
DCA waivers: https://www.dca.ca.gov/licensees/dca_waivers.shtml.

From: Danny <Danny@apothecaryoptions.com>
Sent: Wednesday, April 6, 2022 7:01 AM
To: Mohammadzadeh, Mojgan@DCA <Mojgan.Mohammadzadeh@dca.ca.gov>
Subject: Apothecary Options Order of Corrections

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: danny@apothecaryoptions.com

Danny

From: Mohammadzadeh, Mojgan@DCA <Mojgan.Mohammadzadeh@dca.ca.gov>
Sent: Thursday, April 7, 2022 4:57 PM
To: Danny
Subject: RE: Apothecary Options Order of Corrections

Danny,
I reviewed your corrections and no further action is to be taken at this time.

Thank you

Mojgan Mohammadzadeh, Pharm.D., Inspector
(pronouns: she,her,hers)
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento,Ca.95833
(916) 531-6246 | FAX (916) 574-8618 |
Mojgan.mohammadzadeh@dca.ca.gov
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For the most updated BOP COVID-19 waivers: https://pharmacy.ca.gov/licensees/emergency_declaration.shtml
DCA waivers: https://www.dca.ca.gov/licensees/dca_waivers.shtml

From: Danny <Danny@apothecaryoptions.com>
Sent: Wednesday, April 6, 2022 7:01 AM
To: Mohammadzadeh, Mojgan@DCA <Mojgan.Mohammadzadeh@dca.ca.gov>
Subject: Apothecary Options Order of Corrections

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: danny@apothecaryoptions.com

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1. Ccr 1735.4- Attached is the new label that has the "compounded date" on the label as requested.
2. CCR 1714- Attached is a photo of the de-iced patient will call fridge

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Apothecary Options

Pharmacy/Wholesaler License # (if applicable): 57642 (California)

Physical Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 530-345-7979 Website: www.apothecaryoptions.com

Licensing Company Email: danny@apothecaryoptions.com

Section 2: Personal Information

First: Danny Middle: Nabil Last: Abifadel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Telephone: 530-345-7979 Email: danny@apothecaryoptions.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Mercer University Southern School of Pharmacy			08/00-06/04	
Address		City	State	Zip
3001 Mercer University Dr.		Altanta	GA	30341
Diploma/Degree obtained, if any				
Pharm.D				
School Name			From - To (MM/YY – MM/YY)	
Fullerton Junior College			07/97-06/00	
Address		City	State	Zip
321 E. Chapman Ave		Fullerton	CA	92832
Diploma/Degree obtained, if any				
none				
School Name			From - To (MM/YY – MM/YY)	
Ruben S. Ayala High School			08/93-06/97	
Address		City	State	Zip
14255 Peyton Dr.		Chino Hills	CA	91709
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15-Present	[redacted]Renz Road	Durham	CA	95938
01/06-07/15	[redacted]lorning Rose Way	Chico	CA	95928
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Apothecary Options Compounding Pharmacy			03/20-present	
Business Address		**City**	**State**	**Zip**
3006 Esplanade, Suite i		Chico	CA	95973
Phone	**Title**		**Number of Employed Hours**	
530-345-7979	Owner/PIC		6240	
Description of Duties				
PIC, process, fill, dispense, document, reconcile prescriptions and chemical inventory				

Business Name			From - To (MM/YY – MM/YY)	
Enloe Medical Center			07/04-2/20	
Business Address		**City**	**State**	**Zip**
1531 Esplanade		Chico	CA	95926
Phone	**Title**		**Number of Employed Hours**	
530-332-7819	Staff/Clinical Pharmacist		33,280	
Description of Duties				
process, fill, dispense, and consult patients/md/rn's on medications, perform inventory managment, audit departments that contain stocked medications monthly.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Danny Abifadel, **certify that as the designated representative for**

Apothecary Options,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. dna I am at least 21 years of age;
3. dna I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. dna I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. dna I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. dna I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. dna I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Danny Abifadel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/16/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Danny Abifadel
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/16/2023
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Butte

I, Danny Abifadel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/31/2023
Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See attached CA Jurat

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT **GOVERNMENT CODE § 8202**

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Butte

ANGELA C. COOK
COMM. # 2412056
NOTARY PUBLIC · CALIFORNIA
COUNTY OF BUTTE
Comm. Expires AUG. 28, 2026

Place Notary Seal and/or Stamp Above

Subscribed and sworn to (or affirmed) before me

on this 31st day of March, 2023,
Date *Month* *Year*

by

(1) Danny Nabil Abifadel

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Designated Rep. App.

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Apothecary Options

Pharmacy/MDEG/Wholesaler License # (if applicable): 57642

Physical Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 530-345-7979 Website: www.apothecaryoptions.com

Licensing Company Email: danny@apothecaryoptions.com

Section 2: Personal Information

First: Danny Middle: Nabil Last: Abifadel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 3006 Esplanade, Suite i

City: Chico State: CA Zip: 95973

Telephone: 530-345-7979 Email: danny@apothecaryoptions.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mercer University Southern School of Pharmacy		08/00-06/04	
Address	**City**	**State**	**Zip**
3001 Mercer University Drive	Atlanta	GA	30341
Diploma/Degree obtained, if any			
Pharm.D			

School Name		From - To (MM/YY – MM/YY)	
Fullerton Junior College		07/97-06/00	
Address	**City**	**State**	**Zip**
321 E. Chapman Ave	Fullerton	CA	92832
Diploma/Degree obtained, if any			
none			

School Name		From - To (MM/YY – MM/YY)	
Ruben S. Ayala High School		08/93-06/97	
Address	**City**	**State**	**Zip**
14255 Peyton Dr.	Chino Hills	CA	91709
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/15-Present	[redacted]Renz Road	Durham	CA	95938
01/06-7/15	[redacted]Morning Rose Way	Chico	CA	95928

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Apothecary Options			03/20-Present
Business Address	**City**	**State**	**Zip**
3006 Esplanade, Suite i	Chico	CA	95973
Phone	**Title**		
530-345-7979	Owner/PIC		

Description of Duties

Pharmacist, owner, processing, dispensing, compounding, consultations, all financial aspects of business

Business Name			From - To (MM/YY – MM/YY)
Enloe Medical Center			07/04-2/20
Business Address	**City**	**State**	**Zip**
1531 Esplanade	Chico	CA	95926
Phone	**Title**		
530-332-7899	Staff/Clinical Pharmacist		

Description of Duties

process, fill, dispense, and consult patients/md/rn's on medications, perform inventory managment, audit departments that contain stocked medications monthly.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Danny Abifadel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/16/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Butte

I, Danny Abifadel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/31/23

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See Attached CA Jurat

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT GOVERNMENT CODE § 8202

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], not Notary)

Signature of Document Signer No. 1 *Signature of Document Signer No. 2 (if any)*

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Butte

ANGELA C. COOK
COMM. # 2412056
NOTARY PUBLIC · CALIFORNIA
COUNTY OF BUTTE
Comm. Expires AUG. 28, 2026

Place Notary Seal and/or Stamp Above

Subscribed and sworn to (or affirmed) before me

on this 31st day of March, 2023.
Date *Month* *Year*

by (1) Danny Nabil Abifadel

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Personal History App

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH 04089	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: King's Pharmacy & Compounding Center

Physical Address: 17500 Red Hill Avenue, Suite 250

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (949) 387-0780 Toll Free # (NAC 639.708, NRS 639.23286): (833) 546-4779

Fax: (949) 387-0784 Contact Email: kingsirvine@gmail.com

Website: www.kingspharma.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): ~~Harishma Desai~~ Shari Bonnet

Supervising/Managing Pharmacist NV Pharmacist Registration #: ~~N/A~~ 09819

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): _____

Corporation/Organization Name: Innovative Pharmacy Solutions, Inc

Mailing Address: 17500 Red Hill Avenue, Suite 250

City: Irvine State: CA Zip: 92614

Telephone: (949) 387-0780 Email: kingsirvine@gmail.com

Contact Person Name: Rani Dibbini

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice - President (title) for King's Pharmacy and Comp. Ctr (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Rani Dibbini

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10.10.23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Rani Dibbini hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice - President (title) for King's Pharmacy & Comp Ctr (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 10th day of OCTOBER, 2023

See Attached Certificate

Notary Public

ROBERT STEPHEN MASLAC
Commission # 2339395
Notary Public - California
Orange County
My Comm. Exp DECEMBER 06,2024

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 10th (Date) day of OCTOBER (Month), 20 23 (Year), by

(1) RAMI DIBBINI

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBERT STEPHEN MASLAC
Commission # 2339395
Notary Public - California
Orange County
My Comm.Exp DECEMBER 06,2024

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: AFFIDAVIT FOR PHARMACY LICENSE

Document Date: UNDATED Number of Pages: 10

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rani Dibbini

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/10/2023

Date

Board Use Only	Date Received: 11/2/23	Amount: $500 - Check #161

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	Innovative Pharmacy Solutions, Inc.
Entity No.:	5601124
Registration Date:	03/23/2023
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of September 05, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 142605823

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 1/2/2019 Inspector: Christopher Woo

Firm: KING'S PHARMACY AND COMPOUNDING CENTER Phone: (949) 387-0780

Address: 16205 SAND CANYON AVE #105 City: IRVINE Zip: 92618

Ownership: CORPORATION 2020

Permit #: PHY53835 Permit Exp: ~~2/1/2019~~ DEA#: FK5813882 DEA Exp: 12/31/2021

Date of Self Assessment Form: 6/28/2017 Other Permit #: N/A Date of DEA Inventory: 6/26/2017

Hours M-F: 8:30am to 6pm Hours Saturday closed Hours Sunday: closed

PIC RANI M DIBBINI RPH58852 Administrator ___

RPH Consultant ___

Staff	RPH Name:	License #:	Staff Name:	License #:
	HARISHMA N DESAI	RPH64003	BIANCA CARBAJAL LOEZA	TCH141526
	SHU-TING JUAN	RPH63947	BRIANNA S PARSONS	TCH154651
	MELISSA M MCNAIR	RPH65355	JONATHAN D SCHLATTER	TCH142539
	ALI REZAEI	RPH59458	JONATHAN J NAREZ RODRI	TCH148875
			LANY T PHAM	TCH128488
			MARIA MENDEZ	TCH146227
			SAMANTHA L WHITE	TCH137898

Inspector Remarks:

Routine inspection
Pharmacy located in the Hoag Health Center complex of buildings; compounding specialties include bio-idential hormones, fertility, derm and ENT; delivery via FedEx; compounding room with powder hood.
QS1 computer software is the primary source of record keeping and maintenance.
The following were reviewed: NTC, permits displayed in public view, TCH to RPH ratio with ID badges, self-assessment, compounding self-assessment, DEA biennial inventory, DEA 222 forms via CSOS, controlled substances invoices separated, Schedule II perpetual inventory log, Policy and Procedures for: TCH job description, impaired employee/theft and diversion. Security/keys, sink with hot and cold water, refrigerator and freezer with thermometer, will call area for RPH initials and matching pill to physical description, subscriber alert [goes to kingsirvine@gmail.com], drug stock for out dated medications, DEA 106, reviewed samples of CII, CIII-CV, and non-controlled prescriptions.
CURES: Pharmacy is transmitting weekly.
Drug Wholesaler: McKesson, Anda, Belco, PCCA, Medisca, Letco, Fagron
Reverse Distributor: Rx Reverse Distributors
Outdates are quarantined
Consultation during inspection: observed
QA for Medication Errors Review: QA P&P in place
Patient Centered Labeling/Interpretive Services: Label is patient centered and available in 12 point font, has federal caution for controlled substances, has physical description, order of information is name, drug, strength, direction for use.

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Discussion:

Discussed use of the draft version of the Board compounding self-assessments for most current law versions, and provided a copy of the draft version to RPH Rezaei.

Discussed and explained the Schedule II reconciliation process and provided a copy of the Board audit directions.

Owner Rezaei said CURES reports maintained electronically, and drivers licensed scanned into patient profile.

PIC Dibbini said pharmacist never leaves premises for lunch or breaks.

Discussed with PIC Dibbini and RPH Dibbini of requirement to generate controlled substance printout for refills of C3-5 at least every 72 hours as per CFR 1306.22.

Master formulas and compounding logs kept in binders.

In order to complete this inspection, PIC Dibbini to e-mail Inspector Woo the following by 1/16/2019:

Newly-conducted schedule 2 inventory.

Policies and procedures revisions as per CCR 1735.5 and CCR 1735.8 [both amended 1/1/2017], and regarding:
*Compounding, which establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment, cleaning; maintenance, operation, and other standard operation procedures related to compounding.
*Review of policies and procedures on an annual basis by the Pharmacist-in-Charge and updated whenever changes are implemented.
*Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
*A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
*Procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
*Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
*Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
*Documenation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
*Dates and signatures reflecting all annual reviews of the policies and procedures approved by the Pharmacist-in-Charge.
*Dates and signatures accompanying any revisions to the policies and procedures approved by the Pharmacist-In-Charge.
*Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
*Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperature devices, and actions to take regarding any out of range temperature variations within the pharmacy.
*Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.
*A written quality assurance plan designed to monitor and ensure the integrity, potency, quality and labeled strength of compounded preparations. The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel. The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis. The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality or labeled strength. The quality assurance plan shall include a written procedure for responding to out-of-

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range temperature variations within the pharmacy.

Contact Information
Inspector: Christopher Woo, Pharm.D.
Email: Christopher.Woo@dca.ca.gov

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) [redacted]

Pharmacist (print) Rani Dibbini

Inspector (sign) [redacted]

Inspector (print) Chris Woo

Owner(sign) [redacted]

Owner(print) Rani Dibbini

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

ORDER OF CORRECTION

Date: 1/2/2019 Permit #: PHY53835

Time of Day: 12:34 PM

Name as shown on permit: **KING'S PHARMACY AND COMPOUNDING CENTER**

Address: 16205 SAND CANYON AVE #105 City: IRVINE

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1715.65	Inventory Reconciliation Report of Controlled Substances. In that last Schedule II inventory conducted on 6/26/2017

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) [signature]

Inspector (print) [illegible]

Date 1/2/19

Signed [signature]

Print Name Rani Dhillon

Title Rani Dhillon, Pharm.D.

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59185

NAME: KINGS PHARMACY AND COMPOUNDING CENTER

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

17500 RED HILL AVE #250
IRVINE CA 92614
ORANGE COUNTY

ISSUANCE DATE

AUGUST 7, 2023

EXPIRATION DATE

FEBRUARY 2, 2024

CURRENT DATE / TIME

DECEMBER 4, 2023
9:48:31 AM

LICENSE RELATIONSHIPS

NAME: DESAI, HARISHMA NEIL

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 64003 **PRIMARY STATUS:** CLEAR

Innovative Pharmacy Solutions, Inc d/b/a King's Pharmacy and Compounding Center

List of Officers and Directors

1. Ali Rezaei, Pharm.D. President (55% Ownership)
2. Rani Dibbini, Pharm.D. Vice-President, Secretary (45% Ownership)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Innovative Pharmacy Solutions, Inc d/b/a King's Pharmacy and Compounding Center

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 17500 Red Hill Ave, Suite 250

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (949) 387-0780 Website: www.kingspharma.com

Licensing Company Email: kingsirvine@gmail.com

Section 2: Personal Information

First: Rani Middle: M Last: Dibbini

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 17500 Red Hill Avenue, Suite 250

City: Irvine State: CA Zip: 92614

Telephone: (949) 387-0780 Email: kingsirvine@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
LAB			1992-1996	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Cal State University Northridge			1996-2001	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
University of California, San Diego			2002-2006	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-2023	[redacted] Edgebrook Way	Porter Ranch	CA	91326
2013-2019	[redacted] Dahlia	Irvine	CA	92618
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
King's Pharmacy and Compounding Center			2016-present	
Business Address		**City**	**State**	**Zip**
16205 Sand Canyon Ave, Suite 105		Irvine	CA	92618
Phone	**Title**		**Number of Employed Hours**	
9493870780	Pharm.D., Vice President		12,000	
Description of Duties				
Pharmacist, Owner				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Rani Dibbini, **certify that as the designated representative for**

Innovative Pharmacy Solutions, INC d/b/a King's Pharmacy and Compounding Center,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. x I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. x I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. x I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. x I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. x I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rani Dibbini

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/10/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rani Dibbin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/1/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

CALIFORNIA JURAT GOVERNMENT CODE § 8202

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 1ST (Date) day of NOVEMBER (Month), 2023 (Year), by

(1) RANI DIBBINI

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBERT STEPHEN MASLAC
Commission # 2339395
Notary Public - California
Orange County
My Comm Exp DECEMBER 06,2024

Place Notary Seal and/or Stamp Above

Signature _____
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: DESIGNATED REPRESENTATIVE APPLICATION

Document Date: UNDATED Number of Pages: 9

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: King's Pharmacy and Compounding Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 17500 Red Hill Ave, Suite 250

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 949-387-0780 Website: www.kingspharma.com

Licensing Company Email: kingsirvine@gmail.com

Section 2: Personal Information

First: Ali Middle: _____ Last: Rezaeii

Alias(es, nicknames, name changes, etc.): _____

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address: 17500 Red Hill Ave, Suite 250

City: Irvine State: CA Zip: 92614

Telephone: 949-387-0780 Email: kingsirvine@gmail.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Troy High School		1995 - 1999	
Address	**City**	**State**	**Zip**
2200 East Dorothy Ln	Fullerton	CA	92831
Diploma/Degree obtained, if any			
High School Degree			

School Name		From - To (MM/YY – MM/YY)	
University California at Irvine		1999 - 2002	
Address	**City**	**State**	**Zip**
	Irvine	CA	92697
Diploma/Degree obtained, if any			
Bachelors of Science			

School Name		From - To (MM/YY – MM/YY)	
University California at San Diego		2002-2006	
Address	**City**	**State**	**Zip**
9500 Gilman Dr	La Jolla	CA	92093
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/23 - Current	[redacted]Catania	Newport Coast	CA	92657
01/22 - 04/23	[redacted] Garden Terrace	Irvine	CA	92603
04/20 - 01/22	[redacted]elescope	Newport Coast	CA	92657
06/13 - 04/20	[redacted]Via Rubino	Newport Coast	CA	92657
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
King's Pharmacy and Compounding Center			2011-Present
Business Address	**City**	**State**	**Zip**
510 Superior Ave, Suite 120	Newport Beach	CA	92663
Phone	**Title**		
949-631-4624	President		
Description of Duties			
Pharmacist-in-Change, Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ali, Rezaei

Print Name (First, Last)

A. R

Original Signature (electronic, copies or stamps not accepted)

11/1/23

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ _____

Original Signature Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

CALIFORNIA JURAT

GOVERNMENT CODE § 8202

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 1ST day of NOVEMBER, 2023, by

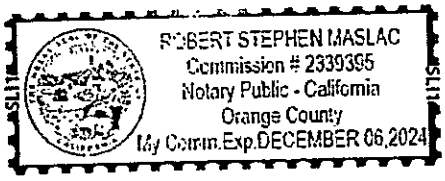
Date *Month* *Year*

(1) ALI REZAEI

(and (2) _____),

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.



Place Notary Seal and/or Stamp Above

Signature _____

Signature of Notary Public

OPTIONAL

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Document Date: UNDATED Number of Pages: 9

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: King's Pharmacy and Compounding Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 17500 Red Hill Ave, Suite 250

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 949-387-0780 Website: www.kingspharma.com

Licensing Company Email: kingsirvine@gmail.com

Section 2: Personal Information

First: Rani Middle: M Last: Dibbini

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 17500 Red Hill Ave, Suite 250

City: Irvine State: CA Zip: 92614

Telephone: 949-387-0780 Email: kingsirvine@gmail.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.) 1794

School Name			From - To (MM/YY – MM/YY)	
LAB			1992-1996	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Cal State University Northridge			1996-2001	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From To (MM/YY – MM/YY)	
University of California, San Diego			2002-2006	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-2023	[redacted]dgebrook Way	Porter Ranch	CA	91326
2013-2019	[redacted]Dahlia	Irvine	CA	92618
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
King's Pharmacy and Compounding Center			2016-Present
Business Address	**City**	**State**	**Zip**
16205 Sand Canyon Ave, Suite 105	Irvine	CA	92618
Phone	**Title**		
949-387-0780	Pharm.D., Vice-President		
Description of Duties			
Pharmacist, Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rani Dibbin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/1/2023

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See Attached Certificate

Notary Public Signature

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

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State of California

County of ORANGE

Subscribed and sworn to (or affirmed) before me on this 1st day of NOVEMBER, 2023, by

Date *Month* *Year*

(1) RAVI DIBBINI

(and (2) _____),

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ROBERT STEPHEN MASLAC
Commission # 2339395
Notary Public - California
Orange County
My Comm.Exp.DECEMBER 06,2024

Place Notary Seal and/or Stamp Above

Signature _____

Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: DESIGNATED REPRESENTATIVE APPLICATION

Document Date: UNDATED Number of Pages: 9

Signer(s) Other Than Named Above: _____

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FK3319058	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-17-2023

KING'S PHARMACY AND COMPOUNDING CENTER
INNOVATIVE PHARMACY SOLUTIONS INC
17500 RED HILL AVE STE 250
IRVINE, CA 92614

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FK3319058	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-17-2023

KING'S PHARMACY AND COMPOUNDING CENTER
INNOVATIVE PHARMACY SOLUTIONS INC
17500 RED HILL AVE STE 250
IRVINE, CA 92614

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-State	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☑ Name Change* * If making a change, provide license #: PH 04223	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☑ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RPC2B, LLC

Physical Address: 61 E Willow St

City: Millburn State: NJ Zip: 07041

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (888) 852-2287 Toll Free # (NAC 639.708, NRS 639.23286): (888) 852-2287

Fax: (973) 327-7256 Contact Email: licensing@rpc2brx.com

Website: www.rpc2brx.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Ze Jiang

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21143

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: n/a	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): n/a

Corporation/Organization Name: RPC2B, LLC

Mailing Address: 61 E Willow St

City: Millburn State: NJ Zip: 07041

Telephone: (888) 852-2287 Email: licensing@rpc2brx.com

Contact Person Name: Ze Jiang

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the pharmacist-in-charge (title) for RPC2B, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Ze Jiang

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/21/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Ze Jiang hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the pharmacist-in-charge (title) for RPC2B, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21st day of April, 2023

Notary Public

HAMID JAMES NOTARY PUBLIC STATE OF NEW JERSEY MY COMMISSION EXPIRES 1-6-2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ze Jiang

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/21/2023

Date

Board Use Only	Date Received: 4-26-23	Amount: 500.00 CC

RPC2B

(888) 852-2287
61 E Willow St
Millburn, NJ 07041
www.rpc2brx.com

To whom it may concern:

Below are the names, titles, and addresses of the officers of RPC2B, LLC:

Name: Shawn Hodges
Title: President & CEO
Address: 6095 Pine Mountain Rd NW, Suite 108, Kennesaw GA 30152

Name: Ze Jiang
Title: Vice President
Address: 61 E Willow St, Millburn NJ 07041

Name: Will Skinner
Title: CFO
Address: 9777 Pyramid Ct, Ste 230, Englewood CO 80112

If you have any questions, please get in touch with me at the pharmacy. Thank you!

Sincerely,

Ze Hua Jiang, PharmD, MBA, BCSCP
Pharmacist-in-Charge
RPC2B, LLC

CSC
251 Little Falls Drive
Wilmington, DE 19808-1674
800.927.9800
302.636.5454 fax

CSC RPC2B, LLC

Matter Number n/a

DELAWARE STATUS SEARCH

www.cscglobal.com

Entity Information

			Search Results Date/Time	04-11-2023	22:23
Entity Name	RPC2B, LLC				
File Number	6911968	Status	Good Standing since 20220714		
Entity Type		Limited Liability	Corp Type		General
Tax Type		Annual L.L.C. Tax	Stock Corporation		No
Residency		Domestic	State		DE
Incorporation Date		20220714			
Renew Date			Expire Date		
Bankruptcy			Bankrupt Date		
Case No					
Orig Incorp Country			Orig Date		
Merged To Number					
Qtrly Filings		False	Last Ann Rpt		
Foreign incorporation date					
Original foreign name					
Original foreign kind		Unknown			

Registered Agent

Agent Name	CORPORATION SERVICE COMPANY			Agent ID	9000014
Address	251 LITTLE FALLS DRIVE				
	WILMINGTON,New Castle				
State	DE	Country	US	Zip	19808

The information above is taken from the records of Delaware's Office of the Secretary of State and reflects information of record as of the thru date listed on this report.CSC cannot and does not independently verify the accuracy or completeness of this information and, accordingly, we make no guaranties or representations about the accuracy or completeness of the information and disclaim any warranties about it and any liability for errors or omissions. If you wish to obtain a certified copy of documents on file or an official good standing, please contact your CSC Customer Service Representative

CSC
251 Little Falls Drive
Wilmington, DE 19808-1674
800.927.9800
302.636.5454 fax

CSC RPC2B, LLC

Matter Number n/a

DELAWARE STATUS SEARCH

www.cscglobal.com

Stock Information

Amendment Number	0	Effective Date		End Date	

Description	Class	Series	Authorized	Par Value	Designated shares

Total Shares Authorized	
No Par Shares	

Filing History (last 5 filings)

Filing Year	Document Code	Pages	Filing Date/Time	Efective Date	Filing Status	Merger Type
2022	LLC	1	20220714T10:19:00:0000	20220714	Archived	

Taxes Due

Tax Year	Filing Fee	Total Tax	Penalty	Interest	Other	Paid	Balance
2023	0.00	300.00	0.00	0.00	0.00	0.00	300.00
2022	0.00	300.00	0.00	0.00	0.00	0.00	300.00

	Tax Balance	600.00

The information above is taken from the records of Delaware's Office of the Secretary of State and reflects information of record as of the thru date listed on this report.CSC cannot and does not independently verify the accuracy or completeness of this information and, accordingly, we make no guaranties or representations about the accuracy or completeness of the information and disclaim any warranties about it and any liability for errors or omissions. If you wish to obtain a certified copy of documents on file or an official good standing, please contact your CSC Customer Service Representative

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

RPC2B, LLC
ZE HUA JIANG
61 E. Willow St.
Millburn NJ 07041

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

05/05/2022 TO 06/30/2023
VALID

28RS00775600
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

Cari Fais
ACTING DIRECTOR

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS

Cari Fa
Acting Direct
Read B

License Information

Accurate as of April 25, 2023 11:29 AM

Return to Search Results

Name: RPC2B, LLC

Address: Millburn,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00775600

License Status: Active

Status Change Reason: License Issuance

Issue Date: 12/13/2019

Expiration Date: 6/30/2023

NO Board Actions. For more information contact New Jersey State Board of Pharmacy (973)504-6450.

Documents

No Public Documents

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: RPC2B, LLC

Pharmacy/Wholesaler License # (if applicable): n/a

Physical Address: 61 E Willow St

City: Millburn State: NJ Zip: 07041

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (888) 852-2287 Website: www.rpc2b.com

Licensing Company Email: licensing@rpc2brx.com

Section 2: Personal Information

First: Ze Middle: Hua Last: Jiang

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Lansing Place

City: Montclair State: NJ Zip: 07043

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)		Yes	No
1.	Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2.	Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		n/a

10/27/23, 10:07 AM
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Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Fox School of Business - Temple University		08/13 - 05/17	
Address	**City**	**State**	**Zip**
1801 Liacouras Walk	Philadelphia	PA	19122
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy - USciences		08/07 - 5/13	
Address	**City**	**State**	**Zip**
600 S 43rd Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Central High School		09/03 - 06/07	
Address	**City**	**State**	**Zip**
1700 W Olney Avenue	Philadephia	PA	19141
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
010/18 - Present	[redacted] Lansing Place	Montclair	NJ	07043
07/17 - 10/18	[redacted] Halsey St, Apt 609T	Newark	NJ	07102
01/16 - 07/17	[redacted] Donato Circle	Scotch Plains	NJ	07076
1/15 - 1/16	[redacted] Valley Road, Apt 9	Montclair	NJ	07043
11/13 - 12/14	[redacted] Ramapo Way	Scotch Plains	NJ	07076
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.		Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

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I, Ze Jiang, **certify that as the designated representative for**

RPC2B, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZHJ I am at least 21 years of age;
3. ZHJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZHJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZHJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZHJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZHJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ze Jiang

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

NOVEMBER 14, 2023

Date

images (225×225)

10/27/23, 10:08 AM

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ZE JIANG

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/2023

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of ESSEX

I, ZE JIANG Yoandri Alvarado, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

18- October, 2023

Date

Subscribed and Sworn to before me this 18 day of October.

YOANDRI ALVARADO
Commission # 50209012
Notary Public, State of New Jersey
My Commission Expires
April 12, 2028

Notary Public Signature

(Seal)

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: _____
File number: _____

Board of Pharmacy Inspection Report

Pharmacy trade name

Corporation name (if not the same)

Owner (as identified on the occasion of this inspection)

Street address

City State ZIP code

(Paste pharmacy label here)

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Name of permit holder _____ Certificate number _____ Expiration date _____

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

Certificate number _____ Expiration date _____

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

Certificate number _____ Expiration date _____

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): _____
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☐ Yes ☐ No)

Permit number _____ Expiration date _____ Hours worked per week _____

1. Is the registered pharmacist-in-charge's current renewal on display? ☐ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☐ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☐ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☐ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R.-1700.14/15] Is a representative inventory of safety closures present? ☐ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☐ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☐ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☐ Yes ☐ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☐ Yes ☐ No
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☐ Yes ☐ No

Print the name of the registered pharmacist who was present for the survey _____ Signature of the registered pharmacist who was present for the survey _____

Signature of the Enforcement Bureau representative _____

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: RPC2B LLC
Street Address: 61 E. Willow St.
City, State, ZIP: Millburn, NJ 07041

Date: 3/8/2023
Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39–7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.		NO DEFICIENCIES		N/A								
2.		Randomly selected										
3.		APIs.										
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

COMMENTS: 2 of 3

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

P F Jiang
PRINTED NAME OF PHARMACIST

SIGNATURE OF PHARMACIST

EB-23A (1/05)

Date: 3/8/2023
Time entered: 9:45 am
Time departed: 1:20 pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: RPC2B

Address: 61 E. Willow St Millburn, NJ 07041

Name and registration number of pharmacist-in-charge:
Ze Jiang 28R10361 6000

(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted:

① (13:39-11A.15(b)12) - The patient compounded prescription label had a BUD of 8/22/2023, however the compounding records for Rx #10000870 did not indicate the "BUD".

* will check MLD for PMP waiver.

3 of 3

Upon further examination of records/documents collected, deficiencies may be noted by this investigator subsequent to the inspection activity.

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

(Signature of the Pharmacist identified above)

EB-33

3/07

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☐ Retail/Community	☐ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☑ Other: Mail Order	☑ Non-sterile Compounding
			☐ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Undefined Pharmacy, LLC

Physical Address: 266 King George Road, Suite C-2

City: Warren State: New Jersey Zip: 07059

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 908-430-7379 Toll Free # (NAC 639.708, NRS 639.23286): 877-395-3220

Fax: 908-430-7379 Contact Email: info@undefinedrx.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Daniel G. Worley Jr.

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23613

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Daniel G. Worley Jr.	NV Pharmacist Registration #: 23613
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Undefined Health, LLC

Corporation/Organization Name: Undefined Pharmacy, LLC

Mailing Address: 266 King George Road, Suite C-2

City: Warren State: New Jersey Zip: 07059

Telephone: 908-430-7379 Email: info@undefinedrx.com

Contact Person Name: Daniel G. Worley Jr.

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

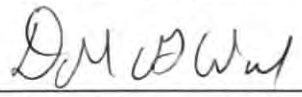
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO & Pharmacist in Charge (title) for Undefined Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Daniel G. Worley Jr.

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

December 26, 2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Daniel G. Worley Jr. hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO & Pharmacist in Charge (title) for Undefined Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26th day of December, 2023

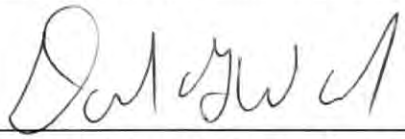
Notary Public

IRYNA MELNYK
Notary Public, State of New Jersey
Comm. # 50203756
My Commission Expires 10/26/2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel G. Worley Jr., CEO & Pharmacist in Charge

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

December 26, 2023

Date

Board Use Only	Date Received: 1/8/24	Amount: $500 - Check #32

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Undefined Pharmacy

Address: 266 King George Road, Suite C-2

City: Warren State: NJ Zip: 07059

I hereby authorize the New Jersey Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
28RS00797700	Active	10/6/2023	6/30/2024

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited N/A ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
[signature]	Agency Servs. Rep.	N.J.	12/27/23	

Undefined Pharmacy

December 26, 2023

Officer & Stockholder Statement

Officer

The **sole officer** for Undefined Pharmacy, LLC is:

Daniel Gary Worley Jr.
CEO & Pharmacist In Charge
(t) 908-430-0831

Home Address:
[redacted]Mount Airy Road
Basking Ridge, NJ 07920

Business Address:
266 King George Road, Suite C-2
Warren, NJ 07059

[redacted]

NJ Pharmacist License #: 28RI03496300

Stockholder

The **sole stockholder** (owns 100%) of Undefined Pharmacy, LLC is Undefined Health, LLC.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UNDEFINED PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE EIGHTEENTH DAY OF DECEMBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "UNDEFINED PHARMACY, LLC" WAS FORMED ON THE FIRST DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Jeffrey W. Bullock, Secretary of State

7493741 8300

SR# 20234254383

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204848930

Date: 12-18-23

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Undefined Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): N/A - pending

Physical Address: 266 King George Road, Suite C-2

City: Warren State: NJ Zip: 07059

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 908-430-7379 Website: N/A

Licensing Company Email: info@undefinedrx.com

Section 2: Personal Information

First: Daniel Middle: Gary Last: Worley

Alias(es, nicknames, name changes, etc.): I have a suffix (Jr.)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Mount Airy Road

City: Basking Ridge State: NJ Zip: 07920

Telephone: [redacted] Email: dworley@undefinedhealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Seton Hall Law School			08/12-05/15
Address	**City**	**State**	**Zip**
1109 Raymond Blvd	Newark	NJ	07102
Diploma/Degree obtained, if any			
JD			

School Name			From - To (MM/YY – MM/YY)
Rutgers University - Ernest Mario School of Pharmacy			08/06-05/12
Address	**City**	**State**	**Zip**
160 Frelinghuysen Rd	Piscataway	NJ	08854
Diploma/Degree obtained, if any			
PharmD			

School Name			From - To (MM/YY – MM/YY)
Delsea Regional High School			
Address	**City**	**State**	**Zip**
242 Fries Mill Road	Franklinville	NJ	08322
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
NA			NA
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			

School Name			From - To (MM/YY – MM/YY
NA			NA
Address	**City**	**State**	**Zip**
NA	NA	NA	NA
Diploma/Degree obtained, if any			
NA			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/21-present	[redacted] Mount Airy Road	Basking Ridge	NJ	07920
07/16-05/21	[redacted] Univeristy Court	South Orange	NJ	07079
08/15-07/16	[redacted] Riverside Station Blvd	Secaucus	NJ	07094
05/12-08/15	[redacted] Carriage City Plz, Apt 1106	Rahway	NJ	07065
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Undefined Pharmacy, LLC			09/23-present	
Business Address		**City**	**State**	**Zip**
266 King George Road, Suite C-2		Warren	NJ	07059
Phone	**Title**		**Number of Employed Hours**	
908-430-7379	CEO & Pharmacist in Charge		640	
Description of Duties				
Pharmacist in Charge of mail order pharmacy in New Jersey				

Business Name			From - To (MM/YY – MM/YY)	
Edenbridge Pharmaceuticals, LLC			01/18-09/23	
Business Address		**City**	**State**	**Zip**
1 Upper Pond Road, Suite D250		Parippany	NJ	07054
Phone	**Title**		**Number of Employed Hours**	
201-479-1336	General Counsel & SVP, BD		10,400	
Description of Duties				
Responsible for all legal and compliance activities of the company, including state licenses. Responsible for all trade and distribution for the company's branded prescription products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Daniel G. Worley Jr., **certify that as the designated representative for**

Undefined Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DGW I am at least 21 years of age;
3. DGW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DGW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DGW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DGW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DGW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Daniel G. Worley Jr.

Print Name (First, Last)

DGWorley

Original Signature (electronic, copies or stamps not accepted)

December 26, 2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel G. Worley Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

December 26, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of _____

I, Daniel G. Worley Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/26/2023

Date

Subscribed and Sworn to before me this 26th day of December, 2023

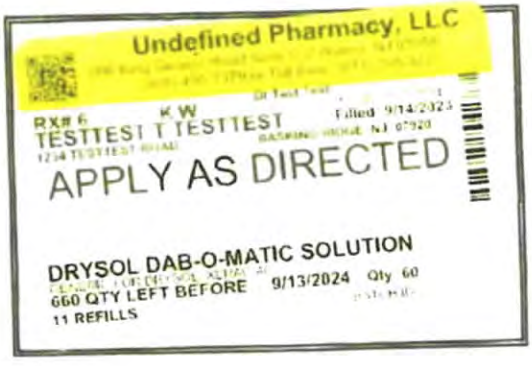
Notary Public Signature

IRYNA MELNYK
Notary Public, State of New Jersey
Comm. # 50203756
My Commission Expires 10/26/2027

(Seal)

NEW PHARMACY
BOARD OF PHARMACY
INSPECTION CONDUCTED
IN CONNECTION WITH A PERMIT APPLICATION FOR A

New
(Retail) → closed door
Pharmacy



Board of Pharmacy please note:
The "Pharmacy Permit / CDS License Approval Notification Letter"
is to be:

☑ Mailed to ☐ Faxed to:

Name and Title: Daniel Worley Name: _____

Address: 266 King Georges Rd Title: _____

Suite C-2 Fax Number: _____

City, State, Zip: Warren, NJ 07059

Revised: 10/2005
ef

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ENFORCEMENT BUREAU

REPORT OF INSPECTION

TO: Board of Pharmacy	FILE # #8-7233-23-812	DATE 9/14/2023
SUBJECT: Undefined Pharmacy 266 King George Road Suite C-2 Warren, NJ 07059		BY: Rachna Patel RPh R.P./Field Representative

REFERENCE:

New pharmacy inspection conducted pursuant to N.J.A.C. 13:39-4.1.

ASPECTS OF THIS INSPECTION MERITING CONSIDERATION:

☐	I	Ownership
☐	II	Location/Proposed Operations
☐	III	Spatial Requirements/Physical Facilities
☐	IV	Storage Facilities
☐	V	Required Signs and Placards
☐	VI	Library
☐	VII	Metrological Equipment
☐	VIII	Dispensing Complements
☐	IX	Record-keeping & Patient Counseling

☑	Enclosed as Attachment #1 is a copy of the filed "Application For Permit to Conduct a Pharmacy" which predicated this inspection.

DETAILS:

A. N.J.S.A. 45:14-75 - Requires that all businesses or enterprises that operate a pharmacy, drug store or render such professional services be registered with and be issued a permit by the Board of Pharmacy. The terms "pharmacy" and "drug store" are defined as establishments or places of business that are required to be operated or managed at all times by registered pharmacists. To satisfactorily conduct a practice of pharmacy, the Board has enacted appropriate rules and regulations that establish minimum standards in regard to: equipment, supplies, physical space, hours of operation and other requisites that may be essential to compound and dispense prescription items for the purpose of offering adequate pharmaceutical services to the public.

B. N.J.S.A. 45:14-70 - Directs, in part, that only upon application on a form prescribed and furnished to the Board, will the Board consider and issue a permit to conduct a new pharmacy.

C. N.J.A.C. 13:39-4.1 - Details the progression, eligibility and requisites involved in the new pharmacy permit application process, namely:

(a) A permit application shall be submitted to the Board by every person or corporation desiring to operate a new pharmacy. Such application shall be made on a form furnished by the Board.

(b) The permit application shall indicate the exact intended location and plan or physical arrangement of the proposed pharmacy area and shall indicate any premises contiguous to, but not necessarily a part of the pharmacy.

(c) The permit application shall bear the exact trade name, if any; the corporate names, if any; the names and addresses of the owners and operators, if a sole proprietorship or partnership; the names and addresses of all officers and stockholders, and the names and addresses of all principals duly licensed to write prescriptions if the pharmacy is a non-publicly held corporation; and the names and addresses of the officers, if a publicly held corporation.

(d) The permit application shall include the name of the pharmacist-in-charge, who shall be a registered pharmacist in good standing in the State of New Jersey.

(e) No person or other business entity shall be eligible for a new permit or a renewal thereof who is not of high moral character or against whom there is pending any indictment or any alleged violation of local, state or federal law pertaining to the practice of pharmacy or the dispensing or controlled dangerous substances or any drug under N.J.S.A. 24:21-2.

(f) A person submitting an application may be interviewed by the Board to review his or her qualifications and eligibility.

(g) Upon approval of the permit application, the Board shall issue a permit number that will allow the applicant to place prescription legend drugs in stock.

D. Consistent with the dictates of N.J.S.A. 45:14-75, N.J.S.A. 45:14-70 and N.J.A.C. 13:39-4.1, this inspection booklet is designed to place at the Board's disposal, a uniform, systematic, comprehensive presentation of all of the data that is essential for the Board to equitably evaluate and consider the applicant's potential compliance with the regulatory requisites as well as to satisfactorily conduct a practice of pharmacy. As required by N.J.A.C. 13:39-4.1, it is the applicant's responsibility and obligation to have available for transfer to the inspector, all the necessary ownership organizational charts, site location specifics and floor plan specifications with accurate dimensions. For those pharmacies that have unusually complex ownership structures, or are to be located in sensitive areas that may adversely impact upon the pharmacy operations, (the Board, in advance of the inspection) will notify the applicant of the additional information that will be required. The applicable sections of the booklet allow for the notification of the presence of any specially requested information, that will be annexed hereto. An index of this report exhibit's attachments appears is enclosed.

E. To assist in the verification that all of the required information has been acquired, the booklet is divided into sequential categories that are designated as follows: Category I - Ownership, Category II - Location/Proposed Operations, Category III - Spatial Allocations and Physical Facilities, Category IV - Storage Facilities, Category V - Required Signs and Placards, Category VI - Library, Category VII - Metrological Equipment, Category VIII - Dispensing Complements, Category IX - Record-keeping and Patient Counseling Requisites. (For those pharmacies that are licensed as a "Pharmacy Department," inspection activity will include a pharmacy department compliance checking procedure form which will be included as an exhibit attachment to this report).

F. When documenting the informational requests contained on the following pages, the inspector places either an "X" or "✓" to indicate non-compliance with that particular statutory requirement. To denote that an inspection activity has been undertaken regarding each of the categories which encompass this inspection procedure, the initials of the inspector and/or inspection party will be placed adjacent to each category of inspection procedure denoted by roman numeral.

G. Prior to departing from the pharmacy, the inspector explains and discusses with the applicant, any deficiencies that may be noted. To avoid any possible future misunderstandings, the applicant is requested to acknowledge through the recording of initials, the deficiencies that were noted in connection with the inspection. The applicant is also invited to add written comments in areas that are provided in the "Comments" section at the bottom of each segment of the inspection "Acknowledgment" portion of this report. Upon the inspector's departure from the pharmacy, a copy of the inspection report's findings is left with the inspected party.

H. New pharmacy inspection procedures are outlined below:

(a) The applicant or their authorized representative or representatives who are present for the inspection, complete pharmacy employee/representative Personnel ID Sheets.

(b) The applicant or authorized representative verifies the accuracy of the information reported on the "Application For Permit To Conduct A Pharmacy" and records, dates and initials any changes made to the copy of the submitted application which is included with this report as an exhibit. If no changes are to made to the Permit Application, the applicant will either "X" or "✓" and initial the statement: "My review of the responses that had been previously recorded in reply to the informational requests of the "Application For Permit To Conduct A Pharmacy" forms are correct, and all declarations remain as reported".

FILED "NEW PHARMACY" APPLICATION REVIEW

☐ My review of the responses that had been previously recorded in reply to the informational requests of the "Application For Permit to Conduct A Pharmacy" forms are correct, and all declarations appear accurately reported.

☐ Changes and/or modifications were required to be made to the filed "Application For Permit To Conduct A Pharmacy." See Attachment #1 for specifics.

[redacted]

Inspection revealed deficiencies regarding the pharmacy's ownership. (13:39-4.1)
Yes ☐ No ☐ (If answered affirmatively, see "Comments" which follow for specific information) ☐ "Y"

A. An ownership organizational chart is attached. ☐*

B. Documentation reflecting a complex ownership structure that requires special consideration is attached. ☐*

C. A supplemental report explaining the ownership structure intricacies is attached. ☐*

Item	Comments
	A list of ownership chart is attached as Exhibit # 1

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted]

Inspection revealed deficiencies regarding the subject pharmacy's location and/or proposed operations (13:39-4.1(b)) ☐*	☐ "Y"

A. A site location, that displays the exact intended location of the pharmacy and all contiguous premises (but not necessarily a Part of the pharmacy) is attached. ☐*

B. The pharmacy is located in a sensitive area that may adversely impact upon the access, egress and the operations of the pharmacy (13:39-5.2). ☐*

C. A supplemental report explaining the proposed operations is attached. ☐*

Item	Comments
	A site location map is attached as Exhibit #2

4

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted]

A. The pharmacy's floor plan specification with accurate dimensions is attached. ☐*	ok	
B. AREA (13:39-5.4(b)) - Occupies a minimum of 150 square feet.	ok	☐ "Y"
C. PRESCRIPTION COUNTER(S) (13:39-5.5) - Not less than 12 total feet in length and 18 inches in width.	ok	☐ "Y"
D. SINK (13:39-5.6) - Is easily accessible to the prescription counter, and is equipped with both hot and cold running water.	ok	☐ "Y"
E. SHELF, DRAWER or CABINET SPACE (13:39-5.7) - Is sufficient for the storage of prescription drugs, chemicals and required equipment.	ok	☐ "Y"
F. CERTIFICATE OF OCCUPANCY - A "Certificate of Occupancy" has been issued by the local building authorities. ☐*	ok	☐ "Y"

Item	Comments
A.	A copy of the pharmacy's floor plan specifications is attached as Exhibit # 3
B.	A copy of the "Certificate of Continued Occupancy" from the Township of Warren. Exhibit #6
	The pharmacy's alarm system documents are attached as Exhibit # 9
	Backup Mechanism = cellular wireless.

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted]

A. A satisfactorily operational refrigerator is present (13:39-5.8(a)12). dk	☐ "√"
B. Controlled substances are to be satisfactorily stored; i.e.: if not dispersed throughout the pharmacy's drug stock inventory, there is an adequately secured and safeguarded storage area for controlled dangerous substances (13:39-5.8(a)4). dk	☐ "√"

Item	Comments
	Future CDS medication storage.
	• CII CDS medications will be stored in a securely locked safe.
	• CIII-CV same as above.

6

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

A. There is present on the building's exterior, a sign that identifies the presence of a pharmacy at the location (13:39-5.3(a)). ☐*	OK ↔ Closed sign	☐ "V"
B. Drug Utilization Review Council placards are posted in two locations (13:39-5.8(a)17).	OK	☐ "V"
C. A sign with the name of the R.P.-in-charge is displayed (13:39-5.3(b)).	OK	☐ "V"
D. "Smoking Prohibited" signs are posted (26:3D-42).	OK	☐ "V"

Item	Comments
	Photographs of the premises on which the pharmacy is to be located are attached as Attachment A pages 9-13

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted]

A. Current editions of suitable reference texts for the below-indicated categories are present (13:39-5.8(a)1):	☐ "V"

1. Comprehensive
2. General Practice of Pharmacy.
3. Drug Interactions.
4. Drug Product Composition.
5. Patient Counseling.

PDF

Listing of Texts Present: Goodman & Gilman → 13th ed.

(Title and Edition/Publication Date)

FDA orange book - online

Facts & Comparisons → online.

B. The current "Drug Utilization Review Council" Formulary (and supplements, if any) is present (13:39:5.8(a)17).	☐ "V"

Invoices were present at the location reflecting "library texts" on order. Yes ☐ No ☐ ☐*

Item	Comments

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted]

A. A Class "A" prescription balance or equivalent electronic device is present (13:39-5.8(a)5). Make: A&D Co. Model Nr: GF-200P Serial Nr: 10392845	☐ "V"
B. A satisfactory set of metric weights is present (13:39-5.8(a)5).	☐ "V"
1. Denominations: 50mg (_), 100mg (_), 200mg (_), 500mg (_), 1Gm (_), 2Gm (_), 5Gm (_), 10Gm (_), 20Gm (_), 50Gm (_) N/A	
C. Volumetric devices capable of measuring from 0.3ml to 500ml are present (13:39-5.8(a)6).	☐ "V"
1. Capacities: 10ml (✓), 25ml (✓), 50ml (_), 100ml (✓), 250ml (_), 500ml (✓).	
2. Glass graduates of a capacity greater than 15 milliliters (4 fluid ounces) [may be double scale and may be of either a cylindrical or conical design] are present. Graduates of a capacity of 15 milliliters or less, [limited to single-scale and cylindrical design] are present.	
(In lieu of graduates of less than 15 milliliter capacities, the Board will accept syringes, pipettes or other acceptable volumetric measuring devices. Present? ☐)	
D. All metrological equipment (balances, scales, weights and automatic counting devices) have been inspected and Sealed by the appropriate Department of Weights and Measures (13:39-5.11). Inspected and sealed on: 7/27/2023 (Date).	☐ "V"

Invoices were present at the location reflecting equipment" on order. Yes ☐ No ☐ ☐*

Item	Comments
A.	The Class "A" prescription balance was an electronic balance
D.	A copy of the "Certificate from Weights + Measures from Somerset County is attached as Exhibit #5.

9

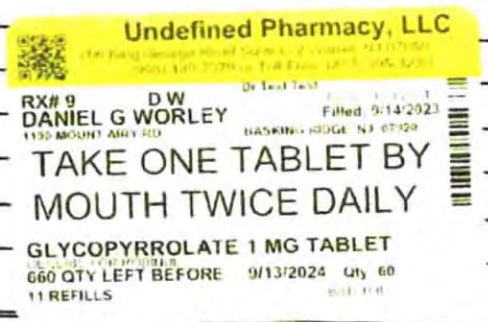
*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

[redacted] DISPENSING COMPLEMENTS

A.	An over-the-counter "Schedule V CDS" record book (13:39-5.8(a)2) is present, if the pharmacy dispenses such medication without a prescription. Do not intend to sell OTC	☐ "V"
B.	A device to permanently file prescriptions (13:39-5.8(a)3) is present. ok	☐ "V"
C.	Prescription labels, which upon dispensing, contain the name, address and telephone number of the pharmacy (13:39-7.12(a)1 and 2)(13:39-5.8(a)14) are present. (An exemplar is attached. ☐*) ok	☐ "V"
D.	Auxiliary labels, to include poison labels (13:39-5.8(a)15) are present. (Exemplar attached. ☐*) ok	☐ "V"
E.	A glass mortar and pestle (minimum of one) is present (13:39-5.8(a)7). ok	☐ "V"
F.	Glass funnels are present (13:39-5.8(a)8). ok	☐ "V"
G.	Stirring rods are present (13:39-5.8(a)9). ok	☐ "V"
H.	Spatulas (minimum of one steel and one composition) are present (13:39-5.8(a)10). ok	☐ "V"
I.	Ointment Tile or parchment pad is present (13:39-5.8(a)11). ok	☐ "V"
J.	An approved counting device or counting tray is present (13:39-5.8(a)13). ok ~~n/a~~	☐ "V"
K.	A suppository mold is present (13:39-5.8(a)16). N/A	☐ "V"

Invoices were present at the location reflecting "dispensing complements" on order. Yes ☐ No ☐ ☐*

Item	Comments



*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

A Patient Profile Record system is in place (13:39-7.19(a)).	☐ "V"
1. The Pharmacy will use a "Manual" Profile Record Keeping System. An exemplar of the form to be used is attached. ☐*	
2. The pharmacy will use an electronic record keeping system that is equipped with Software supplied by DRX.	
B Patient Counseling system (13:39-7.19(e)) et. seq.	
1. There is in place a system where patients refusals to accept offers to counsel will be documented (13:39-7.19(e)3). ☐* → electronically.	☐ "V"
2. For those situations when neither the patient nor the care-giver is physically present, the offer to counsel will be extended (13:39-7.19(e)4) satisfactorily:	☐ "V"
a. By telephone. ☑	
b. Through a printed notification ☐*, that:	
(1) Is printed in a bold, easily read print.	
(2) Is printed on a separate document that will accompany the prescription.	
(3) Will include:	
(a) The hours that the pharmacist will be available.	
(b) The telephone number where the pharmacist will be able to be reached.	
(c) The telephone number is local or will be at no cost to the pharmacy's projected primary patient population.	

Item	Comments
	Customers refusal and acceptance
	of pharmacist's offer to counsel
	will be documented electronically.

11

*If an "X" or "√" denotation appears in the box adjacent to any asterisk which appears on this page, a relevant exhibit attachment is enclosed.

NEW JERSEY BOARD OF PHARMACY

-REPORT OF INSPECTION ACKNOWLEDGMENT-

Name of Pharmacy: Undefined Pharmacy

Address: 266 King Georges Road Suite C-2
Warren, NJ 07059

Name and registration number of pharmacist-in-charge.
Daniel Worley 28210349 6300
(If pharmacist-in-charge is not present, enter name and original R.P. Certificate Number of R.P. on duty)

This is to verify that I have been present during this inspection, and with the exceptions noted in the "comments" below, I acknowledge the existence of the deficiencies that are cited on the appropriate pages of this booklet.

COMMENTS:

SIGNATURE OF PHARMACIST IDENTIFIED ABOVE

12

1	List of ownership
2	One (1) site location map
3	Copy of the pharmacy floor plan specifications with dimensions
4	Statement from Mr. Worley for non-sterile hazardous compounding
5	Copy of Certificate from "Weights & Measures" from the Township of Somerset
6	Copy of a "Certificate of Continued Occupancy" from the Township of Warren
7	Sample of prescription label with drug monograph
8	Pharmacy Personnel Identification Forms
9	Copy of an alarm monitoring certificate from "SimpliSafe"
10	Copies of Temperature Logs
11	Copy of Temperature Policy & Procedures
12	Copy of "Certificate of Formation"
13	Copy of "Certificate of Authority"
14	Copy of "Certificate of Liability Insurance"
15	Copy of State of New Jersey Business Registration Certificate
16	Copy of Department of Treasury-Internal Revenue Service
17	Copy of "Business Trade Name Certificate" from the Township of Somerset
18	Copy of Lease Agreement
19	Copy of Policies and Procedures for Quality Assurance
20	Notarized Affidavit

21	Notarized statement for mail order and commuting

Attachments

Attachment A: Pharmacy Permit Application + Photographs + New Pharmacy Supplemental Checklist

Attachment B: New Pharmacy Booklet

UNDEFINED Pharmacy, Warren, New Jersey
New Pharmacy Inspection
Case File #8-7233-23-812
Applicant Identification #
Supplemental Information

On September 14, 2022, I, Bureau Investigator Rachna Patel, conducted an inspection of the proposed SUBJECT pharmacy. Present at the proposed SUBJECT pharmacy was Pharmacist-In-Charge (RPIC), Daniel Worley (28RI03496300). Mr. Worley completed a "Pharmacy Personnel Identification Form" which is attached as **Exhibit #8.**

The proposed SUBJECT pharmacy is located in Suite #C-2 within King George Plaza. It will be a fifty (50) state mail-order pharmacy with a limited formulary. The proposed SUBJECT pharmacy will not be dispensing medications for walk-in's, or retail customers, nor will they be providing any compliance packaging, repackaging, or compounded products.

The proposed SUBJECT pharmacy will be utilizing DRX software. Par-Med will be their primary wholesaler. The proposed SUBJECT pharmacy will be ordering directly from the manufacturers depending on volume.

The proposed SUBJECT pharmacy does not intend to engage in any sterile, or non-sterile, compounding. A copy of a statement of their business model by Mr. Worley, is marked and attached as **Exhibit #1.**

AREA OF CONCERN:

The proposed SUBJECT pharmacy's business model (refer to Exhibit #1) appears to be under a corporation (Undefined Health, LLC), which also will have ownership in a company (Undefined Care PLLC) owned by physicians who will then contract with other physicians to provide care to patients. As stated in Exhibit #1, the SUBJECT pharmacy will have a "limited formulary of medications (Drysol (aluminum chloride hexahydrate 20%) antiperspirant and glycopyrrolate tablets initially). The formulary will expand after launch of the SUBJECT pharmacy, but will be "limited" to the disease states supported by "Undefined Health LLC".

Mr. Worley stated that Undefined Care, PLLC, is not legally formed and confirmed that the Undefined Care, owned by physicians, is a subsidiary of Undefined Health LLC, which is a web site portal.

Mr. Worley was not able to provide the name of this third-party telehealth provider and which state the business will be registered.

The proposed SUBJECT pharmacy had a monitored security system installed. The monitoring company is SimpliSafe. The SimpliSafe security system is a monthly auto-pay service which includes motion sensors, and means of communication with a battery and cellular backup. The security system was consistent with the requirements set forth in N.J.A.C. 13:39-4.15(b)1. A copy of the contract is marked and attached as **Exhibit #9**.

The proposed SUBJECT pharmacy had sensors and thermometers present to monitor ambient room, refrigerator, and freezer temperatures. The temperatures will be monitored by SensorPush, and in addition, will be recorded electronically. A copy of the temperature monitoring logs, and written policies and procedures pertaining to temperature monitoring and control were obtained. They are marked and attached as **Exhibits #10 and #11**.

The proposed SUBJECT pharmacy had an electronic scale present that had been inspected, tested, and sealed by the Somerset County Office of Weights and Measures on July 27, 2023 (refer to attached **Exhibit #5**).

Dispensing complements were present in the proposed SUBJECT pharmacy on the occasion of the inspection activity.

Mr. Worley relayed that patient refusals, or acceptance of offers to counsel by the pharmacist via telephone would be documented electronically, and on all signed delivery sheets. Additionally, an offer to counsel notice will be included with all delivered prescriptions.

Photographs of the interior of the proposed SUBJECT pharmacy department were taken and are marked and attached as **Attachment A, pages 9 to 53**.

An exit briefing was conducted with Mr. Worley at the conclusion of the inspection activity. He was also informed by this Investigator that the proposed SUBJECT pharmacy was required to open within ninety (90) days of the issuance of the permit and was also required to notify the Board of Pharmacy, in writing, when the pharmacy opened for business, pursuant to the regulations set forth in N.J.A.C. 13:39-4.1(i). After Mr. Worley questions were answered, and satisfied, he verbalized an understanding of such. I then departed the proposed SUBJECT pharmacy.

CERTIFICATION:

I, the undersigned, of full age, employed by the State of New Jersey, Division of Consumer Affairs, Enforcement Bureau – Professional Boards as an Investigator, certify that all of the information contained in this report based upon my knowledge is true. I am aware that if any of the information is willfully false, I am subject to punishment. With respect to the information reported by me, which the context discloses is not based on my personal knowledge, I certify that I have reported in good faith and, to the best of my recollection, an accurate of the information reported to me.

Rachna Patel RPh

Rachna Patel, RPh Investigator

- END OF REPORT -

BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

UNDEFINED PHARMACY
DANIEL GARY WORLEY, JR.
266 King George Road, Suite C-2
Warren NJ 07059

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

10/06/2023 TO 06/30/2024
VALID

Signature of Licensee/Registrant/Certificate Holder

28RS00797700
LICENSE/REGISTRATION/CERTIFICATION #

ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
UNDEFINED PHARMACY
Pharmacy

10/06/2023 TO 06/30/2024
VALID
SIGNATURE

28RS00797700
License/Registration/Certificate # ACTING DIRECTOR

PLEASE DETACH HERE

IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS

Cari Fais
Acting Director
Read Bio

License Information

Accurate as of December 26, 2023 9:58 AM

Return to Search Results

Name: UNDEFINED PHARMACY

Address: Warren,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00797700

License Status: Active

Status Change Reason: License Issuance

Issue Date: 10/6/2023

Expiration Date: 6/30/2024

NO Board Actions. For more information contact New Jersey State Board of Pharmacy (973)504-6450.

Documents

No Public Documents

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4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: I4H Pharmacy, LLC

Physical Address: 11705 Slate Ave. Ste 100

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address): LBX #25676 14005 Live Oak Ave

City: Irwindale State: CA Zip: 91706-1300

Telephone: 951-499-4911 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 951-324-1205 Contact Email: pharmacy@infusionforhealth.com

Website: www.infusionforhealth.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Yatin Kumar Patel

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21172

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:
Name: N/A	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): N/A

Corporation Name: N/A

Mailing Address: N/A

City: N/A State: Zip:

Telephone: N/A Email:

Contact Person Name: N/A

Date of SEC Registration: N/A	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Infusion Management , INC

Corporation/Organization Name: I4H Pharmacy, LLC

Mailing Address: 135 S. State College Blvd., Suite 350

City: Brea State: CA Zip: 92821

Telephone: 951-499-4911 Email: seema@infusionforhealth.com

Contact Person Name: Seema Siddiqui

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: N/A

City: N/A State: Zip:

Telephone: N/A Email:

Contact Person Name: N/A

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: N/A

Business Address: N/A

City: N/A State: Zip:

Telephone: N/A Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for 14H Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Seema Siddiqui

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

10/1/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Seema Siddiqui hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for I4H Pharmacy LLC dba I4H Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 31st day of October, 2023

Notary Public

MELISA YUENWAI GILLESPIE
Notary Public - California
Orange County
Commission # 2358173
My Comm. Expires May 18, 2025

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Jason B Kiroyan Pharmacist Registration #: RPH79355

Pharmacy Name: I4H Pharmacy

Initial each statement below to indicate you have read and agree with the following:

_____ I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

_____ I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

_____ I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

_____ I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

_____ I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved, I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

_____ 6/19/23

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Seema Siddiqui

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

10/1/23

Date

Board Use Only	Date Received: 11/29/23	Amount: $500 - 9652704166 check

Nevada State Board of Pharmacy- Non-Resident Pharmacy Application

I4H Pharmacy, LLC

1. List of all Officers and Directors
    a. Dan McCarty- CEO, Director
    b. Craig Mercer- CFO, Secretary
    c. Seema Siddiqui- President, Pharmacy Operations
2. List of top four stockholders and their percent ownership
    a. I4H Pharmacy is an LLC and therefore does not have any stockholders
    b. I4H Pharmacy, LLC is 100% owned by Infusion Management, Inc. located at 135 S. State College Blvd Ste 350, Brea, CA 92821
3. Personal History Record Application
    a. I4H Pharmacy, LLC does not have shareholders or stockholders

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	14H PHARMACY, LLC
Entity No.:	4148145
Registration Date:	05/01/2018
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of November 26, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 161365220

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: I4H Pharmacy LLC dba I4H Pharmacy

Pharmacy/Wholesaler License # (if applicable): PHY58883

Physical Address: 11705 Slate Ave Ste 100

City: Riverside State: CA Zip: 92505

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 951-499-4911 Website:

Licensing Company Email: pharmacy@infusionforhealth.com

Section 2: Personal Information

First: Jason Middle: Brian Last: Kiroyan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Boot Straps Ct

City: Riverside State: CA Zip: 92507

Telephone: [redacted] Email: jkiroyan@infusionforhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Loma Linda University School of Pharmacy		09/14-05/18	
Address	**City**	**State**	**Zip**
24745 Stewart St	Loma Linda	CA	92350
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
University of California San Diego		09/07 - 06/11	
Address	**City**	**State**	**Zip**
9500 Gilman Dr	La Jolla	CA	92093
Diploma/Degree obtained, if any			
B.S. Biochemistry and Cell Biology			
School Name		**From - To (MM/YY – MM/YY)**	
Redlands high School		06/03-06/07	
Address	**City**	**State**	**Zip**
840 E Citrus Ave	Redlands	CA	92374
Diploma/Degree obtained, if any			
H.S. Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/19 - present	[redacted]Boot Straps Ct	Riverside	CA	92507
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/15-11/19	[redacted]S Erin Way	San Bernardino	CA	92408
From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/06-06/15	[redacted]Fowler Dr	Loma Linda	CA	92354
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
I4H Pharmacy			11/22 - Present
Business Address	**City**	**State**	**Zip**
11705 Slate Ave	Riverside	CA	92505
Phone	**Title**		**Number of Employed Hours**
951-499-4911	Director of Pharmacy		1600
Description of Duties			
Oversee daily operations of pharmacy including intake, filling, and verification of prescriptions			

Business Name			From - To (MM/YY – MM/YY)
Preveon Specialty Pharmacy			07/18 - 11/22
Business Address	**City**	**State**	**Zip**
7223 Church St, A-19	Highland	CA	92346
Phone	**Title**		**Number of Employed Hours**
909-499-4911	Pharmacy Manager		8000
Description of Duties			
Dispensed medications for a specialty setting			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Jason Kiroyan, **certify that as the designated representative for**

I4H Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jason Kiroyan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/22/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason Kiroyan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/22/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Riverside

I, Jason Kiroyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/22/23

Date

Subscribed and Sworn to before me this _____ day of _____.

ANIK PATEL NOTARY PUBLIC

Notary Public Signature

SEE ATTACHED

(Seal)

California Jurat Certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of RIVERSIDE } S.S.

Subscribed and sworn to (or affirmed) before me on this 22 day of September, Month

20 23, by JASON KIROYAN and

Name of Signer (1)

_____, proved to me on the basis of

Name of Signer (2)

satisfactory evidence to be the person(s) who appeared before me.

Signature of Notary Public

ANIK PATEL, COM. # 2251671

For other required information (Notary Name, Commission No. etc.)

ANIK PATEL
COMM. #2416272
Notary Public - California
Riverside County
My Comm. Expires Sep. 16, 2026

Seal

OPTIONAL INFORMATION

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

The certificate is attached to a document titled/for the purpose of

containing _____ pages, and dated _____

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
○ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:

Page # _____ Entry # _____

Notary contact: _____

Other

☐ Affiant(s) Thumbprint(s) ☐ Describe: _____

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California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 11/30/2022 Inspector: Lyle Matthews

Firm: I4H PHARMACY, LLC Phone: (909) 328-4383

Address: 11705 SLATE AVE., SUITE 100 City: RIVERSIDE Zip: 92505

Ownership: CORPORATION

Permit #: LSC00000 PHY00000 Permit Exp: ___ DEA#: ___ DEA Exp: ___

Date of Self Assessment Form: ___ Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 0900 - 1700 Hours Saturday ON-CALL Hours Sunday: ON-CALL

PIC VINSON W CHIEN RPH67580 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:	Staff Name:	License #:
ANGELA S CASTAGNETO	RPH55625	BERTHA TUSCHER	TCH20452
JASON B KIROYAN	RPH79355	JOSUE G HUERTA ZUNIGA	TCH72594

Inspector Remarks:

Performing on-site Change of Ownership sterile compounding renewal inspection at I4H Pharmacy, LLC in Riverside, CA. I4H is short for "Infusion 4 Health." The parent company of I4H pharmacy will be Infusion Management, Inc.. PIC Vinson Chien is present and assisting in the inspection. Infusion Management, Inc. is going to be the new owners of this facility taking over from Brothers Pharmacy (PHY57689 and LSC101565). Current PIC Vinson Chien is seeing the change of ownership through to completion then is planning on staying with Brother's Pharmacy and pharmacist Jason Kiroyan is planning on becoming the new PIC for I4H.

PIC Chien's Contact information is: e-mail: vinsonc@brothershealthcare.com Phone: 909-792-2300

I4H Pharmacy will be a closed door specialty pharmacy that is located in a business park complex in Riverside, CA. The pharmacy's primary business will be to provide specialty pharmacy services to ambulatory infusion centers owned by Infusion For Health and for patients receiving those therapies at home.

The LSC functions largely to support patients on service who also receive the specialty therapies. Services offered will include antibiotics, TPN, hydration, etc. The current pharmacy has not produced any CSP's since January 2021, almost two years ago. No hazardous compounding services are offered. There is a negative pressure room that is

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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INSPECTION REPORT

certified, but there is not a BSC in the room at this point. The room was built for future use. Per PIC Chien, the sterile compounding functions are not a primary focus at this time.

There is a specialty closed door pharmacy, Beeman's Redlands Pharmacy (PHY58185), directly next door in the adjacent suite that is also owned by the same owners as Brother's Pharmacy. It is a closed door pharmacy that also offers primarily outpatient retail prescription and specialty pharmacy services for the hemophilia community. Brothers pharmacy will continue to own Beeman's pharmacy which is directly adjacent to, and in the same physical building as the current Brother's Pharmacy and what will be the new I4H facility. There is no shared access between pharmacies.

LSC Inspection:

The compounding area is a four room suite. There is a prep room which has a sink, emergency eye wash station, supply carts, etc. This room leads into the ISO7 ante room. The ante room leads to two rooms, one ISO7 positive pressure buffer zone and one ISO7 negative pressure hazardous compounding room. The interlocking door system allows only one door to be open at any time. There are large windows between the prep room and ante room, between the prep room and the positive pressure buffer zone, between the ante room and the positive pressure buffer zone, and between the unclassified pharmacist work area and the negative pressure HD room. All doors in the compounding suite are made of glass which allows for visual contact throughout the area.

Compounding Area:

- Flooring: Sheet vinyl coved up the walls. Lines of demarcation are noted by different color sheet vinyl.
- Walls: Clean and washable
- Sink: In prep room
- Emergency Eye Wash Station: In prep room
- Air Pressure Monitoring: Continuous and electronic
- Air vents on lower walls

Prep Room:

- Unclassified
- Stainless steel sink
- Emergency eye wash station
- Stainless steel supply carts
- Door to ante room
- Two So-Low two-door 6-ft refrigerators

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Ante Room:
- ISO7
- Air Exchanges: 63.5 per hour
- Air Pressures: +0.078
- Stainless steel carts
- Cleaning solutions and dedicated mops
- PPE

Positive Pressure Buffer Zone:
- ISO7
- Air Exchanges: 71.8 per hour
- Air Pressures: +0.050
- Stainless steel supply carts
- Stainless steel work tables
- Pinnacle TPN compounder inside ISO5 LFH
- Pass Thru window between positive pressure buffer zone and ante room.
- ISO5 NuAire 6-ft LFH

Laminar Flow Hood/Cabinet: ISO5 NuAire 6-ft LFH

Non-Hazardous Drugs Prepared:
- Antibiotics, TPN, hydration.
- No CSP's have been compounded since January 2021.

Negative Pressure Buffer Zone:
- ISO7
- Air Exchanges: 47.9 per hour
- Air Pressures: -0.020
- There is no BSC in this room at this time and it is not functions.
- The room is built and ready for future use as needed.

Biological Safety Cabinet: N/A

Hazardous Drugs Prepared: N/A

CSTD System: N/A

Certification: CERTS (Controlled Environmental Regulatory Testing Services) 8/8/2022

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INSPECTION REPORT

- Environmental Viable Sampling: All samples passed
- HEPA Filtration: Passed

Smoke Tests: Viewed with PIC during inspection. Performed under dynamic conditions.

PPE/Garbing: All required PPE is available.

BUD's: Per USP797. No extended BUD's are assigned.

Labeling: All required elements are present.

Master Formula: All master formulas are kept in MedKeeper. The file was reviewed with PIC during inspection.

Compounding Log: Reviewed for TPN compounded on 1/7/2021 for Pt. A.K.. All required elements are present.

Inventory:

- Pre-Mixed Drips: N/A
- Outsourcing 503B: N/A
- TPN: Compounded internally using Pinnacle Compounder. No TPN has been compounded since Jan. 2021.
- 503A: N/A
- Connector System: Mini Bag Plus

Controlled Substances: No controlled substances are in inventory in the pharmacy.

Cleaning Documentation: Recorded on MedKeeper. Reviewed during inspection.

Refrigerator/Freezer Logs: Recorded on Med Keeper. Refrigerators are alarmed and notify PIC if out of range.

Logs are stored in MedKeeper for all daily, weekly, and monthly, quarterly, etc. required processes. Manual log sheets are completed and the data is transferred into MedKeeper. If any required process is not entered into MedKeeper, the dashboard will notify the PIC of any element that is missing.

Security: Cameras are in place. Facility doors are alarmed.

Cleaning Agents: Peridox-RTU, PREempt-RTU, Sterile IPA

Training:

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INSPECTION REPORT

- All required training documents are recorded in MedKeeper.
- Annual didactic test
- Fingertip Testing annually
- Media Fill annually
- Aseptic Technique written test annually
- Compounding observation evaluation annually
- Cultural sensitivity
- Infusion Pump Training
- Fire Safety
- Two HIPAA modules completed annually
  - HIPAA rules and regulations
  - Fraud, Waste, and Abuse

Policy and Procedures:

- Began with purchasing Med Pass policy and procedure manual.
- Edited versions of original Policies to incorporate Brothers Pharmacy specific procedures will now be transitioned to I4H policies.
- Reviewed annually by PIC.
- Policies are adjusted along the way with an updated revision date as policies are updated.

Quality Assurance Program:

- Process Validation:
  - Gentamicin 80mg/100ml. Dynalabs tested 3/16/22. Potency: 103.2%

Wholesaler: Amerisource Bergen

Reverse Distributor: PharmaLink

Education During Inspection:

If there have been changes in your policies and procedures in the last year, please provide an electronic copy of the new or changed polices and procedures. You may do this by sending a disk or CD to the Board or e-mail the new policies and procedures to: compounding.pharmacy@dca.ca.gov. Please use the pharmacy's California sterile compounding license number (LSC or NSC and five-digit number) on the disk, CD, or in the subject line of the e-mail to ensure proper identification. Please identify or list the changes to your procedures. Failure to identify or list the changes will hinder timely renewal.

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Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Discussion:

Follow-up questions may be referred to Inspector Matthews at lyle.matthews@dca.ca.gov or to (909) 255-2973.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) VINSON CHIEN

Inspector (sign) Lyle Matthews, PhD

Inspector (print) Lyle Matthews, Pharm.D

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO. PHY 58883 ISSUE DATE MARCH 01, 2023

I4H PHARMACY, LLC
11705 SLATE AVE STE 100
RIVERSIDE CA 92505

The above is licensed with the State Board of Pharmacy as a Limited Liability Company.

LIMITED LIABILITY COMPANY
JASON KIROYAN PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL MARCH 01, 2024 RECEIPT NUMBER 00000000

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

/24/23
/24/23

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

November 21, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: I4H PHARMACY, LLC

License Type: PHARMACY

License Number: PHY 58883

Status: ACTIVE

Issue Date: 03/01/2023

Expiration Date: 03/01/2024

Address of Record: 11705 SLATE AVE STE 100 RIVERSIDE, CA 92505

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FI2626642	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-27-2023

I4H PHARMACY, LLC
DBA I4H PHARMACY
11705 SLATE AVE
STE 100
RIVERSIDE, CA 92505

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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FI2626642	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-27-2023

I4H PHARMACY, LLC
DBA I4H PHARMACY
11705 SLATE AVE
STE 100
RIVERSIDE, CA 92505

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Form DEA-223 (9/2016)

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FA3605930
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	■ Other: Specialty	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Patient Service Center LLC DBA Access Therapy Center

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Toll Free # (NAC 639.708, NRS 639.23286): 888-796-8154

Fax: 877-370-0142 Contact Email: licensing@raremedpsc.com

Website: www.raremedpsc.com

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220) Justin Smerker

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable). 23661

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: John James Coll Jr.	NV Pharmacist Registration #: NA
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA
Name: NA	Credentials: NA	%: NA

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): NA

Corporation Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Date of SEC Registration: NA	SEC Registration Number: NA	Stock Exchange Symbol: NA

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): PSC Holding Co LLC

Corporation/Organization Name: Patient Service Center LLC DBA Access Therapy Center

Mailing Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Email: licensing@raremedpsc.com

Contact Person Name: Timothy Davis, Advisor

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Contact Person Name: NA

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: NA

Business Address: NA

City: NA State: NA Zip: NA

Telephone: NA Email: NA

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for Patient Service Center LLC DBA Access Therapy Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Gordon J. Vanscoy

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/11/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Gordon J. Vanscoy hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member (title) for Patient Service Center LLC DBA Access Therapy Center (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11 day of December, 2023

Notary Public

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gordon J. Vanscoy, Managing Member

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/11/2023

Date

Board Use Only	Date Received: 12/19/23	Amount: $500 - check 1085

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Patient Service Center LLC
Request Type:	Subsistence Certificate
Request No.:	026227425
Receipt No.:	000786336
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	July 29, 2023
Status:	Active

Issuance Date: November 29, 2023
File No.: 0013534450

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Patient Service Center LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, PA, 15205

Phone:
Owner: TIMOTHY JAMES DAVIS

LICENSE

License No: AA0004861814
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 11/02/2023
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

STEVEN ZAHN	11/2/2023 11:56:02 AM	John James Coll - RP455047
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, PA, 15205

Phone:
Owner: TIMOTHY JAMES DAVIS

LICENSE

License No: AA0004861814
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 11/02/2023
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Commonwealth of Pennsylvania Department of State
Bureau of Professional and Occupational Affairs

Pharmacy

License Number
PP483136

Expiration Date
08/31/2025

Active

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

OFFICIAL DOCUMENT

READ THE FOLLOWING INFORMATION CAREFULLY CONCERNING YOUR LICENSE:

1. SIGN THE WALLET CARD AND CERTIFICATE WHERE INDICATED
2. DETACH THE WALLET CARD AND CERTIFICATE AT PERFORATION

Pennsylvania Licensing System (PALS)

Visit our website at: www.pals.pa.gov to renew your license, change your personal or license address, or order duplicate licenses.

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

DISPLAY THIS CERTIFICATE PROMINENTLY • NOTIFY AGENCY WITHIN 10 DAYS OF ANY CHANGE

Commonwealth of Pennsylvania
Department of State
Bureau of Professional and Occupational Affairs
PO BOX 2649 Harrisburg PA 17105-2649

23 0211996

License Type
Pharmacy

ACCESS THERAPY CENTER
JOHN JAMES COLL
304 MERCHANT LANE
PITTSBURGH, PA 15205

License Status
Active

Initial License Date
11/02/2023

Expiration Date
08/31/2025

License Number
PP483136

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature

ALTERATION OF THIS DOCUMENT IS A CRIMINAL OFFENSE UNDER 18 PA.C.S.§. 4911

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA3605930	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-17-2023

ACCESS THERAPY CENTER
304 MERCHANT LN
PITTSBURGH, PA 15205

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA3605930	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-17-2023

ACCESS THERAPY CENTER
304 MERCHANT LN
PITTSBURGH, PA 15205

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

12/18/2023

License Information

ACCESS THERAPY CENTER

304 MERCHANT LANE
PITTSBURGH, Pennsylvania 15205

Board/Commission:	State Board of Pharmacy	Status Effective Date:	11/02/2023
LicenseType:	Pharmacy	Issue Date:	11/02/2023
Specialty Type:		Expiration Date:	08/31/2025
License Number:	PP483136	Last Renewal:	
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
JOHN JAMES COLL	Pharmacist Manager	Pharmacist	RP455047	Active	11/02/2023	09/30/2024

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Patient Service Center LLC DBA Access Therapy Center

Pharmacy/Wholesaler License # (if applicable): NV: Pending PA:PP483136

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: John Middle: James Last: Coll

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Fox Run Drive

City: Venetia State: PA Zip: 15367

Telephone: [redacted] Email: jcoll@raremedpsc.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	NA

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Duquesne University		08/16 - 05/20	
Address	**City**	**State**	**Zip**
600 Forbes Ave	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Doctor of Pharmacy - PharmD			

School Name		From - To (MM/YY – MM/YY)	
Duquesne University		08/09 - 05/13	
Address	**City**	**State**	**Zip**
600 Forbes Ave	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Bachelor of Science (Biology) - BS			

School Name		From - To (MM/YY – MM/YY)	
Seton La Salle High School			
Address	**City**	**State**	**Zip**
1000 McNeilly Road	Pittsburgh	PA	15226
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - Present	[redacted] Fox Run Drive	Venetia	PA	15367
02/15 - 01/21	[redacted] Cheston St	Pittsburgh	PA	15227
05/10 - 02/15	[redacted] S. 12th St	Pittsburgh	PA	15227

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
RareMed Solutions			03/21 - Present
Business Address	**City**	**State**	**Zip**
200 Industry Drive	Pittsburgh	PA	15275
Phone	**Title**	**Number of Employed Hours**	
833-676-7273	Manager, Pharmacy Operations	5150	
Description of Duties			
dispense prescriptions, counsel patients, oversee technicians, manage inventories, maintain records, oversee operations, review regulatory compliance, maintain vendor relationships, manage SOP and QA positions			

Business Name			From - To (MM/YY – MM/YY)
Rite Aid Pharmacy			07/20 - 03/21
Business Address	**City**	**State**	**Zip**
2501 Saw Mill Run Blvd	Pittsburgh	PA	15234
Phone	**Title**	**Number of Employed Hours**	
412-882-0500	Staff Pharmacist	1350	
Description of Duties			
dispense prescriptions, counsel patients, oversee technicians, manage inventories, maintain records,			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	NA	NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, John James Coll, **certify that as the designated representative for**

Patient Service Center LLC DBA Access Therapy Center,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JC I am at least 21 years of age;
3. JC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

John, Coll

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/13/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Coll

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/13/23

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, John Coll, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/13/2023

Date

Subscribed and Sworn to before me this 13 day of December 2023

Amy Dovie

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

This document is to confirm the single designated officer for each corporation as listed below. No other officers have been appointed:

Patient Service Center LLC:

Officer	Ownership	Home Address	Title
Gordon Vanscoy	(0%)	[redacted] Galleon Drive, Naples, FL 34102	Managing Member

PSC Holding Co LLC:

Officer	Ownership	Home Address	Title
Gordon Vanscoy	(0%)	[redacted] Galleon Drive, Naples, FL 34102	Managing Member

PSC Pass Co LLC:

Officer	Ownership	Home Address	Title
Gordon Vanscoy	(0%)	[redacted] Galleon Drive, Naples, FL 34102	Managing Member

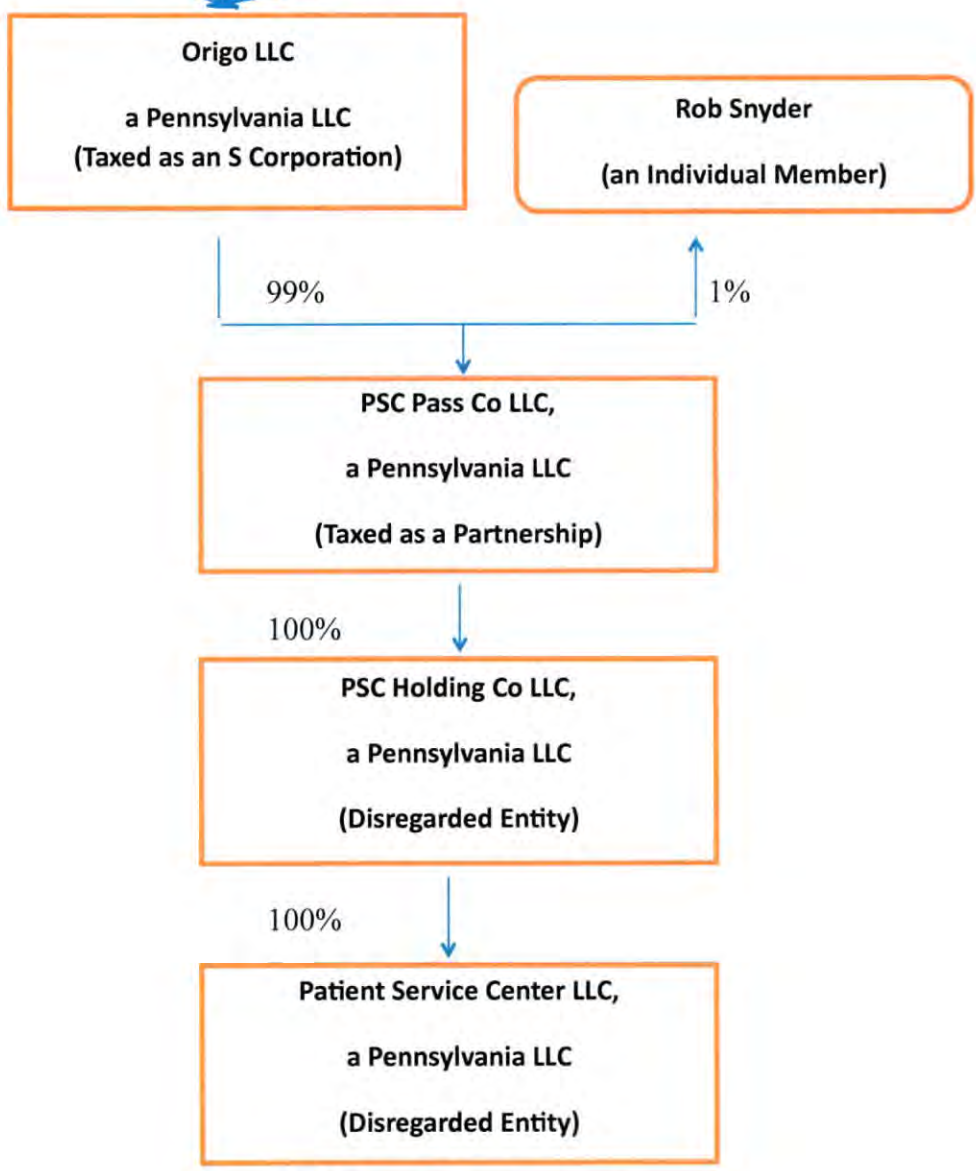
Origo LLC:

Officer	Ownership	Home Address	Title
Gordon Vanscoy	(16.83502%)	[redacted] Galleon Drive, Naples, FL 34102	Managing Member

The diagram on the following page represents the updated ownership structure and percentages through multiple layers of corporations to the ultimate individuals and percentages as exhibited.

Patient Service Center LLC
Org Chart
September 8, 2023

	Gordon Vanscoy	Tim Davis	Doug Gebhard	Rob Snyder SLAT	Alissa Snyder SLAT	Gordon Vanscoy, Jr.	Gannon Vanscoy	Total
Voting%	66.6668	16.6666	0	8.3333	8.33333	0	0	100
Economic%	16.83502	16.83502	16.83503	7.91245	7.91245	16.83502	16.8352	100



DBA Access Therapy Center

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Access Therapy Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP483136 (Pennsylvania)

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: Timothy Middle: James Last: Davis

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Meadow Drive

City: Beaver Falls State: PA Zip: 15010

Telephone: [redacted] Email: tdavis@raremedpsc.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh School of Pharmacy		08/97 - 12/00	
Address	**City**	**State**	**Zip**
3501 Terrace Street	Pittsburgh	PA	15261
Diploma/Degree obtained, if any			
Doctor of Pharmacy - PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Pittburgh College of Art and Sciences		08/93 - 05/97	
Address	**City**	**State**	**Zip**
4200 Fifth Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Bachelors of Science (Neuroscience) - BS			

School Name		From - To (MM/YY – MM/YY)	
Carnegie Mellon University		08/92 - 05/93	
Address	**City**	**State**	**Zip**
5000 Forbes Avenue	Pittsburgh	PA	15213
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Blackhawk High School		08/88 - 06/92	
Address	**City**	**State**	**Zip**
500 Blackhawk Road	Beaver Falls	PA	15010
Diploma/Degree obtained, if any			
High School Dimploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/01 - Present	[redacted] Meadow Drive	Beaver Falls	PA	15010
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Raremed Solutions			05/19 - Present	
Business Address	**City**		**State**	**Zip**
200 Industry Drive	Pittsburgh		PA	15275
Phone	**Title**			
833-676-7273	None			
Description of Duties				
Investor				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			04/19-12/20	
Business Address	**City**		**State**	**Zip**
1120 Stevenson Mill Road Suite 400	Coraopolis		PA	15108
Phone	**Title**			
855-726-8479	General Manager			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations. Fulfill liaison role to CEO.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			12/17-12/20	
Business Address	**City**		**State**	**Zip**
6715 Tippecanoe Road Suite C1	Canfield		OH	44406
Phone	**Title**			
855-726-8479	General Manager			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations. Fulfill liaison role to CEO.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			04/12-12/20	
Business Address	**City**		**State**	**Zip**
24 Summit Park Drive	Pittsburgh		PA	15275
Phone	**Title**			
855-726-8479	General Manager			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations. Fulfill liaison role to CEO.				

Business Name			From - To (MM/YY – MM/YY)	
Rochester Health Mart Pharmacy			01/15-12/18	
Business Address	**City**		**State**	**Zip**
176 Virginia Avenue 3rd Floor	Rochester		PA	15274
Phone	**Title**			
724-987-6085	Owner/Pharmacist			
Description of Duties				
Dispense prescriptions, manage complaince & legal, counsel patients, manage inventory, oversee technicians.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Beaver Falls Health Mart Pharmacy			12/12-12/18
Business Address	**City**	**State**	**Zip**
1314 7th Avenue	Beaver Falls	PA	15010
Phone	**Title**		
724-384-0766	Owner/Pharmacist		
Description of Duties			
Dispense prescriptions, manage complaince & legal, counsel patients, manage inventory, oversee technicians.			

Business Name			From - To (MM/YY – MM/YY)
Beaver Health Mart Pharmacy			01/07-09/16
Business Address	**City**	**State**	**Zip**
601 Third Street	Beaver	PA	15009
Phone	**Title**		
724-774-7979	Owner/Pharmacist		
Description of Duties			
Dispense prescriptions, manage complaince & legal, counsel patients, manage inventory, oversee technicians.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

TIMOTHY DAVIS
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12-18-2023
Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12-18-2023
Date

Subscribed and Sworn to before me this 18 day of December 2023

Amy Dovie
Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Access Therapy Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP483136 (Pennsylvania)

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: Gannon Middle: Michael Last: Vanscoy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Poinciana Ave

City: Miami State: FL Zip: 33133

Telephone: [redacted] Email: gmvanscoy@raremed.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		04/19-04/20	
Address	**City**	**State**	**Zip**
4200 5th Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Masters (Pharmacy Business Administration) - MPBA			

School Name		From - To (MM/YY – MM/YY)	
University of Miami		08/09-05/13	
Address	**City**	**State**	**Zip**
1320 S Dixie Hwy	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
Bachelor Business Administration - BBA			

School Name		From - To (MM/YY – MM/YY)	
Hempfield Area High School		08/02-06/06	
Address	**City**	**State**	**Zip**
4345 PA-136	Greensburg	PA	15601
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Community School of Naples		08/07-05/09	
Address	**City**	**State**	**Zip**
13275 Livingston Road	Naples	FL	34102
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Greensburg Central Catholic		08/06-05/07	
Address	**City**	**State**	**Zip**
911 Armory Drive	Greensburg	PA	15601
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/21 - Present	[redacted] Poinciana Ave	Miami	FL	33131
03/20-06/21	[redacted]7th St S	Naples	FL	34102
09/13 - 03/20	[redacted]Desbrosses Street	New York	NY	10013
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Raremed Solutions			From - To (MM/YY – MM/YY): 05/19 - Present
Business Address: 200 Industry Drive	City: Pittsburgh	State: PA	Zip: 15275
Phone: 833-676-7273	Title: Member - VP of Markets & Analytics		
Description of Duties: Oversee business development opportunites and the Analytics team.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gannon Vanscoy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/23

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, Gannon Vanscoy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/2023

Date

Subscribed and Sworn to before me this 18 day of December 2023

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Access Therapy Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP483136 (Pennsylvania)

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: Gordon Middle: James Last: Vanscoy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: 160-46-0201 Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Galleon Drive

City: Naples State: FL Zip: 34102

Telephone: [redacted] Email: gvanscoy@raremed.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Duquesne University		08/84-05/86	
Address	**City**	**State**	**Zip**
600 Forbes Avenue	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Doctor of Pharmacy - PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		08/78-05/84	
Address	**City**	**State**	**Zip**
4200 Fifth Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Bachelors of Science (Pharmacy) - BS			

School Name		From - To (MM/YY – MM/YY)	
South Allegheny High School		08/74-06/78	
Address	**City**	**State**	**Zip**
2743 Washington Blvd	McKeesport	PA	15133
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - Present	[redacted] Galleon Drive	Naples	FL	34102
08/13-06/20	[redacted] 7th St. S.	Naples	FL	34102

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Raremed Solutions			05/19 - Present	
Business Address		**City**	**State**	**Zip**
200 Industry Drive		Pittsburgh	PA	15275
Phone	**Title**			
833-676-7273	CEO			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			04/19-12/20	
Business Address		**City**	**State**	**Zip**
1120 Stevenson Mill Road Suite 400		Coraopolis	PA	15108
Phone	**Title**			
855-726-8479	CEO			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			12/17-12/20	
Business Address		**City**	**State**	**Zip**
6715 Tippecanoe Road Suite C1		Canfield	OH	44406
Phone	**Title**			
855-726-8479	CEO			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Specialty Pharmacy			04/12-12/20	
Business Address		**City**	**State**	**Zip**
24 Summit Park Drive		Pittsburgh	PA	15275
Phone	**Title**			
855-726-8479	CEO			
Description of Duties				
Oversee business development, finance, human resources, compliance, contracting, legal, strategy, and operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gordon Vanscoy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, Gordon Vanscoy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/2023

Date

Subscribed and Sworn to before me this 18 day of December 2023.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Access Therapy Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP483136 (Pennsylvania)

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: Douglas Middle: Allen Last: Gebhard

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Hickory Heights Drive

City: Bridgeville State: PA Zip: 15017

Telephone: [redacted] Email: dgebhard@raremed.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		08/09 - 04/10	
Address	**City**	**State**	**Zip**
4200 Fifth Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Masters (Business Administration) - MBA			

School Name		From - To (MM/YY – MM/YY)	
University of Pittsburgh		08/03 - 04/09	
Address	**City**	**State**	**Zip**
4200 Fifth Avenue	Pittsburgh	PA	15260
Diploma/Degree obtained, if any			
Doctor of Pharmacy - PharmD			

School Name		From - To (MM/YY – MM/YY)	
Manheim Central High School		08/99 - 06/03	
Address	**City**	**State**	**Zip**
400 Adele Avenue	Manheim	PA	17545
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16 - Present	[redacted]Hickory Heights Drive	Bridgeville	PA	15017
06/10 - 05/16	[redacted]Providence Place	Providence	RI	02903

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Raremed Solutions			03/18 - Present
Business Address	**City**	**State**	**Zip**
200 Industry Drive	Pittsburgh	PA	15275
Phone	**Title**		
833-676-7273	President - PIC - Member		
Description of Duties			
Establishing and carrying out organizational and departmental procedures, goals, and policies.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Doug Gebhard

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/23

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, Doug Gebhard, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/23

Date

Subscribed and Sworn to before me this 18 day of December 2023.

Amy Dovie

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Access Therapy Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PP483136 (Pennsylvania)

Physical Address: 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Mailing Address (if different from physical address): 304 Merchant Lane

City: Pittsburgh State: PA Zip: 15205

Telephone: 888-796-8154 Website: www.raremedpsc.com

Licensing Company Email: licensing@raremedpsc.com

Section 2: Personal Information

First: Gordon Middle: James Last: Vanscoy JR

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] 7th St S

City: Naples State: FL Zip: 34102

Telephone: [redacted] Email: gjvanscoy@raremed.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Duke University: The Fuqua School of Business			07/15-05/17	
Address		City	State	Zip
100 Fuqua Dr		Durham	NC	27708
Diploma/Degree obtained, if any				
Masters Degree (Business Administration) - MBA				
School Name			From - To (MM/YY – MM/YY)	
Carnegie Mellon University			08/06-05/10	
Address		City	State	Zip
5000 Forbes Ave		Pittsburgh	PA	15213
Diploma/Degree obtained, if any				
Bachelors of Science - BS				
School Name			From - To (MM/YY – MM/YY)	
Hempfield Area High School			08/02-06/06	
Address		City	State	Zip
4345 PA-136		Greensburg	PA	15601
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/21 - Present	[redacted]7th St. S.	Naples	FL	34102
04/19-12/20	[redacted]Brickell Bay Dr	Miami	FL	33131
05/17-03/19	[redacted] Mountain Laurel Dr	Euless	TX	76039
01/10-05/17	[redacted]7th St S	Naples	FL	34102
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Raremed Solutions			12/20-Current
Business Address	**City**	**State**	**Zip**
200 Industry Drive	Pittsburgh	PA	15275
Phone	**Title**		
833-676-7273	VP Business Operations		
Description of Duties			
Managing Finance, HR, Communications, & Facilities Teams			

Business Name			From - To (MM/YY – MM/YY)
American Airlines			05/17-12/20
Business Address	**City**	**State**	**Zip**
1 Skyview Dr	Ft Worth	TX	76155
Phone	**Title**		
855-726-8479	Supervisor, Controller Services		
Description of Duties			
Managing Finance, Communications, Analytics			

Business Name			From - To (MM/YY – MM/YY)
United Airlines			06/16-08/16
Business Address	**City**	**State**	**Zip**
233 S Waker Dr	Chicago	IL	60606
Phone	**Title**		
800-864-8331	Intern		
Description of Duties			
Finance Projects			

Business Name			From - To (MM/YY – MM/YY)
GreenCare US LLC			08/12-05/15
Business Address	**City**	**State**	**Zip**
4630 Arnold Ave	Naples	FL	34104
Phone	**Title**		
239-288-2222	President		
Description of Duties			
Managed All Aspects of Company			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gordon Vanscoy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/18/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Beaver

I, Gordon Vanscoy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/18/2023

Date

Subscribed and Sworn to before me this 18 day of December 2023

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
AMY DOVIE - Notary Public
Beaver County
My Commission Expires October 21, 2026
Commission Number 1427778

(Seal)

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-State	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Specialty Pharmacy	☑ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BioPlus Specialty Pharmacy Services, LLC

Physical Address: 4740 Victory Lane Suite C

City: Indianapolis State: Indiana Zip: 46203

Mailing Address (if different from physical address): P.O. Box 162088

City: Altamonte Springs State: Florida Zip: 32716

Telephone: 888-292-0744 Toll Free # (NAC 639.708, NRS 639.23286): 888-292-0744

Fax: 800-269-5493 Contact Email: License@bioplusrx.com

Website: https://bioplusrx.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Andrew J. Russell

Supervising/Managing Pharmacist NV Pharmacist Registration #: 22559

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Andrew J. Russell	NV Pharmacist Registration #: 22559
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation N/A

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): Bioplus Parent, LLC

Corporation/Organization Name: BioPlus Specialty Pharmacy Services, LLC

Mailing Address: 220 Virginia Ave

City: Indianapolis State: Indiana Zip: 46204

Telephone: 317-488-6000 Email: license@bioplusrx.com

Contact Person Name: Kimberly Bourcier

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mark Montgomery

Print Name of Authorized Person

Mark Montgomery

Original signature of Authorized Person (copies or stamps not accepted)

11/7/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding.

Affidavit for Pharmacy License

I, Andrew J. Russell hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 31 day of October, 20 23

Notary Public

KRISTI BRAZIEL
NOTARY PUBLIC
SEAL
My Comm. Exp. 08/21/2031
Comm. #NP0751305
Montgomery County
STATE OF INDIANA

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Montgomery - President/CEO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 11/7/23

Board Use Only	Date Received: 11/24/24	Amount: $500 - Check 03190045

BioPlus®
Specialty Pharmacy

Ownership

BioPlus Parent, LLC – 100% Direct Owner

[redacted] Virginia Avenue
Indianapolis, IN 46204
Tax ID: 85-0609453

BioPlus Parent, LLC – Director/Manager List

Paul Edward Marchetti
[redacted] Manitou Road
Westport, CT 06880
0% ownership interest

Danielle Anne Swenson
[redacted] W 5th Street
Ship Bottom, NJ 08008
0% ownership interest

Vincent Edward Scher
[redacted] Serenity Court
Indianapolis, IN 46280
0% ownership interest

BioPlus Parent, LLC – Officer List

Paul Edward Marchetti - President
[redacted] Manitou Road
Westport, CT 06880
0% ownership interest

Kathleen Susan Kiefer – Secretary
[redacted] Morningside Drive
Indianapolis, IN 46240
0% ownership interest

Vincent Edward Scher - Treasurer
[redacted] Serenity Court
Indianapolis, IN 46280
0% ownership interest

Eric Kenneth Noble – Assistant Treasurer
[redacted] Lions Head Dr., Apt. A
Indianapolis, IN 46260
0% ownership interest

BioPlus Specialty Pharmacy

BioPlus Specialty Pharmacy Services, LLC
Tax ID#59-2920860

Directors/Manager

Paul Edward Marchetti
[redacted] Manitou Road
Westport, CT 06880
0% ownership interest

Danielle Anne Swenson
[redacted] W 5th Street
Ship Bottom, NJ 08008
0% ownership interest

Vincent Edward Scher
[redacted] Serenity Court
Indianapolis, IN 46280
0% ownership interest

Officers

Mark Montgomery (President)
[redacted] Whitesell Dr.
Winter Park, FL 32789
0% ownership interest

Vincent Edward Scher (Treasurer)
[redacted] Serenity Court
Indianapolis, IN 46280
0% ownership interest

Kathleen Susan Kiefer (Secretary)
[redacted] Morningside Drive
Indianapolis, IN 46240
0% ownership interest

Eric Kenneth Noble (Assistant Treasurer)
[redacted] Lions Head Dr., Apt. A
Indianapolis, IN 46260
0% ownership interest

Elvin Montanez (COO/Managing Employee)
[redacted] Lakay Drive
Longwood, FL 32779
0% ownership interest

State of Florida
Department of State

I certify from the records of this office that BIOPLUS SPECIALTY PHARMACY SERVICES, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 6, 2020, effective December 28, 1988.

The document number of this limited liability company is L20000120596.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on April 27, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the First day of June, 2023

Secretary of State

Tracking Number: 1167757507CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

FLORIDA DEPARTMENT OF STATE
Division of Corporations

May 7, 2020

COGENCY GLOBAL

Re: Document Number L20000120596

The Articles of Conversion, and Articles of Organization were filed May 6, 2020, with an organizational date deemed effective December 28, 1988, for BIOPLUS SPECIALTY PHARMACY SERVICES, LLC, the resulting Florida Limited Liability Company.

The certification you requested is enclosed.

To maintain "active" status with the Division of Corporations, an annual report must be filed yearly between January 1st and May 1st beginning in the year following the file date or effective date indicated above. If the annual report is not filed by May 1st, a $400 late fee will be added. **It is your responsibility to remember to file your annual report in a timely manner.**

A Federal Employer Identification Number (FEI/EIN) will be required when this report is filed. Contact the IRS at 1-800-829-4933 for an SS-4 form or go to www.irs.gov.

Should you have any further questions concerning this matter, please feel free to call (850) 245-6051, the Registration Filing Section.

KYLE D BRUMBLEY
Regulatory Specialist II
Division of Corporations

Letter Number: 020A00009419

Account number: I20000000088

Amount charged: 155.00

State of Florida

Department of State

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The document number of this company is L20000120596.

I further certify that said company has paid all fees due this office through December 31, 2020, and its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventh day of May, 2020

Laurel M. Lee
Secretary of State

CR2E022 (01-11)

Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.

11/6/2023 12:40:48 PM

Signature of Inspector | Date/Time | Signature of Owner/Representative

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
BioPlus Specialty Pharmacy Services, LLC
4740 Victory Lane
Suite C
Indianapolis IN 46203
Phone: 8882920744
Owner:
Ownership Type:

LICENSE
License No: 60006895A
Profession: Pharmacy
License Type: Pharmacy
4740 Victory Lane
Suite C
Indianapolis IN 46203
Phone: 8882920744

Inspection Type:	Pharmacy Inspection
Inspection Date:	11/6/2023
Result:	Pass

Remarks: Safe bolted to floor. Not planning on controls at this time. 60006895A

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
BioPlus Specialty Pharmacy Services, LLC
4740 Victory Lane
Suite C
Indianapolis IN 46203
Phone: 8882920744
Owner:
Ownership Type:

LICENSE
License No:
Profession: Pharmacy
License Type: Pharmacy
4740 Victory Lane
Suite C
Indianapolis IN 46203
Phone: 8882920744

Inspection Type:	Pharmacy Inspection
Inspection Date:	9/29/2023
Result:	Pass

Remarks: No tech training. Will have a DEA and CSR but no controls at this time. No compounding. No immunizations. Building and securtity in place to proceed with licensing. Sections of this inspection were left blank because they do not apply to the business model of the pharmacy.
Questions: Timothy Thomas 317-753-4000 tithomas@pla.IN.gov

Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding

Emergency Drug Kits/Crash Carts
Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

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Signature of Inspector

9/29/2023 11:29:04 AM

Date/Time

Signature of Owner/Representative

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Pharmacy

License Number	Expire Date
60006895A	12/31/2025

BioPlus Specialty Pharmacy Services, LLC

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Pharmacy

License Number	Expire Date
60006895A	**12/31/2025**

BioPlus Specialty Pharmacy Services, LLC

Signature

State of Indiana

DEMOGRAPHIC INFORMATION

Name: BioPlus Specialty Pharmacy Services, LLC

ADDRESS INFORMATION

Line 1: 4740 Victory Lane
Line 2: Suite C
City/State/Zip: Indianapolis IN 46203
County: Marion

LICENSE INFORMATION

Lic #: 60006895A
Status: Active
Method: Application
Profession: Pharmacy Board
Issued: 9/29/2023
Type: Pharmacy
Expiration: 12/31/2025
Secondary: Closed Door (III)

DISCIPLINE INFORMATION

RELATED LICENSES

Lic #	Name		
License Type: CSR-Pharmacy	License Status: Pending Application	Relationship: Same Licensee	

SPECIALTY INFORMATION

No Specialty Information

INSPECTION INFORMATION

Inspection Type: Pharmacy Inspection Report
Inspection Date:
Inspection Grade:

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB3712329	07-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-08-2024

BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
4740 VICTORY LN STE C
INDIANAPOLIS, IN 462036076

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FB3712329	07-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-08-2024

BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
4740 VICTORY LN STE C
INDIANAPOLIS, IN 462036076

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: BioPlus Specialty Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 4740 Victory Lane, Suite C

City: Indianapolis State: IN Zip: 46203

Mailing Address (if different from physical address): P.O. Box 162088

City: Altamonte Springs State: FL Zip: 32716-2088

Telephone: 888-292-0744 Website: https://www.bioplusrx.com

Licensing Company Email: license@bioplusrx.com

Section 2: Personal Information

First: Andrew Middle: Joseph Last: Russell

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Terrill Lane

City: Brownsburg State: IN Zip: 46112

Telephone: [redacted] Email: arussell@bioplusrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Butler University			8/2002 - 5/2008	
Address		City	State	Zip
4600 Sunset Ave		Indianapolis	IN	46208
Diploma/Degree obtained, if any				
PharmD				
School Name			From - To (MM/YY – MM/YY)	
Tipton High School			8/98 - 5/2002	
Address		City	State	Zip
619 S Main St		Tipton	IN	46072
Diploma/Degree obtained, if any				
Indiana Academic Honors Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/18 - Present	[redacted] Terrill Lane	Brownsburg	IN	46112
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/15 - 05/18	[redacted] Cuyahoga Ct	South Lyon	MI	48178
From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/15 06/15	[redacted] Hidden Lake Way	Northville	MI	48168
From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/10 - 02/15	[redacted] Iris Drive	Brownsburg	IN	46112
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioPlus Specialty Pharmacy Services, LLC			07/23-Present	
Business Address		**City**	**State**	**Zip**
4740 Victory Lane, Suite C		Indianapolis	IN	46203
Phone	**Title**		**Number of Employed Hours**	
689.262.2539	Pharmacist in Charge		960	
Description of Duties	Oversight of all pharmacy operations including legal/regulatory as the responsible pharmacist.			

Business Name	Express Scripts		From - To (MM/YY – MM/YY)	
			01/20 – 07/23	
Business Address		**City**	**State**	**Zip**
4750 E 450 S		Whitestown	IN	46075
Phone	**Title**		**Number of Employed Hours**	
	Staff Pharmacist Sr. Manager		7440	
Description of Duties	Oversight of all 3rd shift pharmacy operations, including automated warehouse, inventory, packing, shipping, and all licensed personnel			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Andrew J. Russell, **certify that as the designated representative for**

BioPlus Specialty Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AR I am at least 21 years of age;
3. AR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andrew J. Russell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/16/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew J. Russell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-16-24
Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Montgomery

I, Kristi Braziel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-16-24
Date

Subscribed and Sworn to before me this 16 day of January.

Notary Public Signature

KRISTI BRAZIEL
Comm. Exp. 08/12/2031
Comm. #NP0751305
NOTARY SEAL PUBLIC
My Montgomery County
STATE OF INDIANA
(Seal)

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-State	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Specialty Pharmacy	☑ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: BioPlus Specialty Pharmacy Services, LLC

Physical Address: 1831 Chestnut Street

City: St. Louis State: MO Zip: 63103

Mailing Address (if different from physical address): PO Box 162088

City: Altamonte Springs State: FL Zip: 32716

Telephone: 888-292-0744 Toll Free # (NAC 639.708, NRS 639.23286): 888-292-0744

Fax: 800-269-5493 Contact Email: license@bioplusrx.com

Website: www.bioplusrx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Joshua J. Boudeman

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24018

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services In/Into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Joshua J. Boudeman	NV Pharmacist Registration #: 24018
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): BioPlus Parent, LLC

Corporation/Organization Name: BioPlus Specialty Pharmacy Services, LLC

Mailing Address: 220 Virginia Ave

City: Indianapolis State: IN Zip: 46204

Telephone: 317-488-6000 Email: license@bioplusrx.com

Contact Person Name: Kimberly Bourcier

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Mark Montgomery

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/9/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Mark Montgomery hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for BioPlus Specialty Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Mark Montgomery

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 9th day of November, 20 23

Marsha Sue Brown

Notary Public

MARSHA SUE BROWN
Notary Public - State of Florida
Commission # HH 304419
My Comm. Expires Dec 18, 2026
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Montgomery, President/CEO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 11/17/23

Board Use Only	Date Received: 12/20/23	Amount: $500 check 63133450

State of Florida
Department of State

I certify from the records of this office that BIOPLUS SPECIALTY PHARMACY SERVICES, LLC is a limited liability company organized under the laws of the State of Florida, filed on May 6, 2020, effective December 28, 1988.

The document number of this limited liability company is L20000120596.

I further certify that said limited liability company has paid all fees due this office through December 31, 2023, that its most recent annual report was filed on April 27, 2023, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the First day of June, 2023

Secretary of State

Tracking Number: 1167757507CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

FLORIDA DEPARTMENT OF STATE
Division of Corporations

May 7, 2020

COGENCY GLOBAL

Re: Document Number L20000120596

The Articles of Conversion, and Articles of Organization were filed May 6, 2020, with an organizational date deemed effective December 28, 1988, for BIOPLUS SPECIALTY PHARMACY SERVICES, LLC, the resulting Florida Limited Liability Company.

The certification you requested is enclosed.

To maintain "active" status with the Division of Corporations, an annual report must be filed yearly between January 1st and May 1st beginning in the year following the file date or effective date indicated above. If the annual report is not filed by May 1st, a $400 late fee will be added. **It is your responsibility to remember to file your annual report in a timely manner.**

A Federal Employer Identification Number (FEI/EIN) will be required when this report is filed. Contact the IRS at 1-800-829-4933 for an SS-4 form or go to www.irs.gov.

Should you have any further questions concerning this matter, please feel free to call (850) 245-6051, the Registration Filing Section.

KYLE D BRUMBLEY
Regulatory Specialist II
Division of Corporations

Letter Number: 020A00009419

Account number: I20000000088

Amount charged: 155.00

State of Florida

Department of State

I certify from the records of this office that BIOPLUS SPECIALTY PHARMACY SERVICES, LLC, is a limited liability company organized under the laws of the State of Florida, filed on May 6, 2020, with an organizational date deemed effective December 28, 1988.

The document number of this company is L20000120596.

I further certify that said company has paid all fees due this office through December 31, 2020, and its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Seventh day of May, 2020

Laurel M. Lee
Secretary of State

CR2E022 (01-11)

Articles of Conversion
For
"Other Business Entity"
Into
Florida Limited Liability Company

The Articles of Conversion **and attached Articles of Organization** are submitted to convert the following **"Other Business Entity" into a Florida Limited Liability Company** in accordance with s.605.1045, Florida Statutes.

1. The name of the "Other Business Entity" immediately prior to the filing of the Articles of Conversion is:
BioPlus Specialty Pharmacy Services, Inc.
(Enter Name of Other Business Entity)

2. The "Other Business Entity" is a corporation
(Enter entity type. Example: corporation, limited partnership, general partnership, common law or business trust, etc.)

First organized, formed or incorporated under the laws of Florida
(Enter state, or if a non-U.S. entity, the name of the country)

on December 28, 1988.
(date of organization, formation or incorporation)

3. The name of the Florida Limited Liability Company as set forth in the **attached Articles of Organization:**
BioPlus Specialty Pharmacy Services, LLC
(Enter Name of Florida Limited Liability Company)

4. If not effective on the date of filing, enter the effective date:_____.
(The effective date: Cannot be prior to date of receipt or filed date nor more than 90 calendar days after the date this document is filed by the Florida Department of State.)
Note: If the date inserted in this block does not meet the applicable statutory filing requirements, this date will not be listed as the document's effective date on the Department of State's records.

5. The plan of conversion has been approved in accordance with all applicable statutes.

6. The "Converted or Other Business Entity" has agreed to pay any members having appraisal rights the amount to which such members are entitled under ss. 605.1006 and 605.1061-605.1072, F.S.

FILED
2020 MAY -6 PM 1:34
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

Signed this 6th day of May ,2020.

Signature of Authorized Representative of Limited Liability Company:

Signature of Authorized Representative: _____
Printed Name: Stephen C. Vogt Title: President

Signature(s) on behalf of Other Business Entity: [See below for required signature(s)]

Signature: _____
Printed Name: Stephen C. Vogt Title: President

Signature: _____
Printed Name: _____ Title: _____

Signature: _____
Printed Name: _____ Title: _____

Signature: _____
Printed Name: _____ Title: _____

Signature: _____
Printed Name: _____ Title: _____

Signature: _____
Printed Name: _____ Title: _____

If Florida Corporation:
Signature of Chairman, Vice Chairman, Director, or Officer.
If Directors or Officers have not been selected, an Incorporator must sign.

If Florida General Partnership or Limited Liability Partnership:
Signature of one General Partner.

If Florida Limited Partnership or Limited Liability Limited Partnership:
Signatures of **ALL** General Partners.

All others:
Signature of an authorized person.

Fees:

Articles of Conversion:	$25.00
Fees for Florida Articles of Organization:	$125.00
Certified Copy:	$30.00 (Optional)
Certificate of Status:	$5.00 (Optional)

ARTICLES OF ORGANIZATION FOR FLORIDA LIMITED LIABILITY COMPANY

ARTICLE I - Name:
The name of the Limited Liability Company is:

BioPlus Specialty Pharmacy Services, LLC

(Must contain the words "Limited Liability Company, "L.L.C.," or "LLC.")

ARTICLE II - Address:
The mailing address and street address of the principal office of the Limited Liability Company is:

Principal Office Address:	**Mailing Address:**
376 Northlake Blvd.	376 Northlake Blvd.
Altamonte Springs, FL 32701	Altamonte Springs, FL 32701

ARTICLE III - Registered Agent, Registered Office, & Registered Agent's Signature:
(The Limited Liability Company cannot serve as its own Registered Agent. You must designate an individual or another business entity with an active Florida registration.)

The name and the Florida street address of the registered agent are:

Stephen C. Vogt
Name

376 Northlake Blvd.
Florida street address (P.O. Box **NOT** acceptable)

Altamonte Springs FL 32701
City Zip

Having been named as registered agent and to accept service of process for the above stated limited liability company at the place designated in this certificate, I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relating to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent as provided for in Chapter 605, F.S..

Registered Agent's Signature (REQUIRED)

(CONTINUED)

ARTICLE IV-
The name and address of each person authorized to manage and control the Limited Liability Company:

Title: "AMBR" = Authorized Member "MGR" = Manager	**Name and Address:**
AMBR	BioPlus Specialty Pharmacy Services Holdings, Inc. 376 Northlake Blvd. Altamonte Springs, FL 32701
MGR	Stephen C. Vogt, President 376 Northlake Blvd. Altamonte Springs, FL 32701
MGR	H. Stephen Garner, Vice President 376 Northlake Blvd. Altamonte Springs, FL 32701

(Use attachment if necessary)

ARTICLE V: Other provisions, if any.

REQUIRED SIGNATURE: SCVogt

Signature of a member or an authorized representative of a member
This document is executed in accordance with section 605.0203 (1) (b), Florida Statutes. I am aware that any false information submitted in a document to the Department of State constitutes a third degree felony as provided for in s.817.155, F.S.

Stephen C. Vogt
Typed or printed name of signee

Filing Fees

$125.00 Filing Fee for Articles of Organization and Designation of Registered Agent
$ 30.00 Certified Copy (Optional) **$ 5.00 Certificate of Status (Optional)**

STATE OF MISSOURI
BOARD OF PHARMACY

OBSERVATION REPORT

MAILING ADDRESS
MISSOURI BOARD OF PHARMACY
PO BOX 625
JEFFERSON CITY, MO 65102
(573) 526-6985
(573) 526-3464 FAX
PHARMACY@PR.MO.GOV

NAME/ADDRESS OF PHARMACY OR DRUG DISTRIBUTOR	LICENSE NUMBER	CLASS	INSPECTION DATE
BioPlus Specialty Pharmacy Services, LLC 1831 Chestnut St. St. Louis MO 63103	2023044219	A, J, M	11/1/2023

PHARMACIST OR MANAGER-IN-CHARGE	PIC/MIC LICENSE NO
Joshua Boudeman	2011026558

PHONE	Fax	Email
8882920744	8336702942	jboudeman@bioplusrx.com

INSPECTION TYPE: **Initial**

Inspector: Dan Vandersand

Acknowledged By: Joshua Boudeman

Observations:

-Initial inspection satisfactory.

Comments:

BioPlus®
Specialty Pharmacy

BioPlus Specialty Pharmacy Services, LLC

Tax ID#59-2920860

Directors/Managers

Paul Marchetti (Director/Manager)

Danielle Swenson (Director/Manager)

Officers

Mark Montgomery (President)

Vincent Scher (Director/Manager)

Kathleen Kiefer (Secretary/Officer)

Eric Noble (Assistant Treasurer/Officer)

Elvin Montanez (COO/Managing Employee)

BioPlus Specialty Pharmacy

Ownership

BioPlus Parent, LLC – 100% Direct Owner

220 Virginia Avenue
Indianapolis, IN 46204

Tax ID: 85-0609453

BioPlus Parent, LLC – Director/Manager List

Paul Edward Marchetti

Danielle Anne Swenson

Vincent Edward Scher

BioPlus Parent, LLC – Officer List

Paul Edward Marchetti – President

Kathleen Susan Kiefer – Secretary

Vincent Edward Scher - Treasurer

Eric Kenneth Noble – Assistant Treasurer

State of Missouri

Missouri Department of Commerce and Insurance
Division of Professional Registration
Missouri Board of Pharmacy

Pharmacy

Class A, J, M

VALID THROUGH OCTOBER 31, 2025
ORIGINAL CERTIFICATE/LICENSE NO. 2023044219
Joshua J Boudeman - 2011026558
BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
BIOPLUS SPECIALTY PHARMACY SERVICES, LLC
JOSHUA BOUDEMAN, PIC
1831 CHESTNUT ST
SAINT LOUIS MO 63103
USA

EXECUTIVE DIRECTOR

DIVISION DIRECTOR

The Division of Professional Registration and its boards are open during the regular business hours of 8:00a.m. to 5:00p.m. Monday through Friday, excluding state holidays (https://oa.mo.gov/commissioner/state-holidays).

Did you know that there is a drop box located in the front of the Professional Registration building? Individuals may leave items for the division and its boards any time. We do ask that all items be placed in a sealed envelope labeled with the board name or name of the individual if not located in a board.

Missouri Division of Professional Registration

PR Home (https://pr.mo.gov/)

Detail

Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	BioPlus Specialty Pharmacy Services, LLC
Profession Name:	Pharmacy
Licensee Number:	2023044219
Expiration Date:	10/31/2025
Original Issue Date:	11/1/2023
Address:	Joshua Boudeman, PIC
Address Con't:	1831 Chestnut St
City, State Zip:	Saint Louis, MO 63103
County:	St. Louis City
Practitioner DBA Name:	BioPlus Specialty Pharmacy Services, LLC
Certification Type:	
Classification:	Class A, J, M
Current Discipline Status:	None

The Division of Professional Registration and its boards are open during the regular business hours of 8:00a.m. to 5:00p.m. Monday through Friday, excluding state holidays (https://oa.mo.gov/commissioner/state-holidays).

Did you know that there is a drop box located in the front of the Professional Registration building? Individuals may leave items for the division and its boards any time. We do ask that all items be placed in a sealed envelope labeled with the board name or name of the individual if not located in a board.

Board of Pharmacy

PR Home (https://pr.mo.gov/) » Pharmacy Home (https://pr.mo.gov/pharmacists.asp) » Pharmacy Licensee Search (https://pr.mo.gov/pharmacy-licensee-search.asp)

Pharmacy Detail

Pharmacy Primary Source Verification

The licensee search function of this website provides data extracted from our database and constitutes a Primary Source Verification.

Licensee Name:	Boudeman, Joshua J
Profession Name:	Pharmacist
Licensee Number:	2011026558
Expiration Date:	10/31/2024
Original Issue Date:	8/10/2011
Address:	
Address Con't:	
City, State Zip:	Saint Louis, MO 63116
County:	St. Louis City
Practitioner DBA Name:	
Classification:	

Current Discipline Status:	None

Certification Type:	**Effective Date:**	**Expiration Date:**
NOI - Administration By Protocol	10/11/2022	10/31/2024
NOI - Administration By Medical Prescription Order	10/11/2022	10/31/2024

Board of Pharmacy (https://pr.mo.gov/pharmacists)
3605 Missouri Boulevard
P.O. Box 625

Jefferson City, MO 65102-0625
573.751.0091 Telephone
573.526.3464 Fax
800.735.2966 TTY
800.735.2466 Voice Relay
MissouriBOP@pr.mo.gov (mailto:MissouriBOP@pr.mo.gov)
https://pr.mo.gov/pharmacists (https://pr.mo.gov/pharmacists)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler BioPlus Specialty Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1831 Chestnut Street

City St. Louis State MO Zip 63103

Mailing Address (if different from physical address) PO Box 162088

City Altamonte Springs State FL Zip 32716

Telephone 888-292-0744 Website www.bioplusrx.com

Licensing Company Email license@bioplusrx.com

Section 2: Personal Information

First Joshua Middle J. Last Boudeman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted] Federer Place

City St. Louis State MO Zip 63116

Telephone [redacted] Email jboudeman@bioplusrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St Louis College of Pharmacy at University of Health Sciences + Pharmacy		08/05 - 05/11	
Address	**City**	**State**	**Zip**
1 Pharmacy Place	St. Louis	MO	63110
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Olympia High School		08/01 - 05/05	
Address	**City**	**State**	**Zip**
7832 N 100 East Rd	Stanford	IL	61774
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/15 - present	[redacted] Federer Pl	St. Louis	MO	63116
12/11 - 06/15	[redacted] Sidney St	St. Louis	MO	63104

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioPlus Specialty Pharmacy Services, LLC			09/23 - Present	
Business Address		**City**	**State**	**Zip**
1831 Chestnut Street		St. Louis	MO	63103
Phone	**Title**		**Number of Employed Hours**	
888-292-0744	Pharmacist in Charge		40/week	
Description of Duties				
Responsible for the entire pharmacy facility				

Business Name			From - To (MM/YY – MM/YY)	
Walgreen Co.			08/11 – 09/23	
Business Address		**City**	**State**	**Zip**
3527 Chouteau Ave		St. Louis	MO	63103
Phone	**Title**		**Number of Employed Hours**	
314-771-2900	Pharmacy Manager		42/week	
Description of Duties				
Responsible for the entire pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		n/a
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Joshua J. Boudeman, **certify that as the designated representative for**

BioPlus Specialty Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JJB I am at least 21 years of age;
3. JJB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JJB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JJB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JJB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JJB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Joshua J. Boudeman
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-20-23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joshua J. Boudeman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-30-23

Date

Please have this section completed in the presence of a Notary Public.

State of Missouri, ss. County of St. Louis City

I, Joshua J. Boudeman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-30-23

Date

Subscribed and Sworn to before me this 30th day of November 2023

Notary Public Signature

MARK A NICHOLAS
Official Seal
Notary Public - State of Illinois
My Commission Expires Dec 8, 2024

(Seal)

400

Cardinal Health
13651 Dublin Ct, 2nd Floor
Stafford, TX 77477
281.749.4000 Main Tel.

cardinalhealth.com

CardinalHealth

January 17, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Dear Nevada State Board of Pharmacy Representative,

RE: New Out of State Pharmacy License Application

Attached is our application for a new out-of-Nevada Pharmacy license, along with supporting documentation and payment.

The Cardinal Health Pharmacy Services, LLC Pharmacy is a non-drug dispensing Pharmacy Service Center providing remote medication order entry and review for hospitals.
All administration of medications is handled at the client's physical location. This center does not purchase, store, compound, distribute or dispense any pharmaceuticals.

Should you have any questions or concerns, I can be reached at 847-887-1324 or via email at Natacha.Gomez@cardinalhealth.com

Respectfully,

Natacha N. Gomez
Project Manager

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☑ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Non-drug dispensing pharmacy service center providing remote medication order entry and review for hospitals.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Remote Order Entry

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Cardinal Health Pharmacy Services, LLC

Physical Address: 7000 Cardinal Place, Suite 1D

City: Dublin State: Ohio Zip: 43017

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 877-244-5763 Toll Free # (NAC 639.708, NRS 639.23286): 877-244-5763

Fax: 614-210-0824 Contact Email: natacha.gomez@cardinalhealth.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Tracy Michallow

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19731

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Tracy Michallow	NV Pharmacist Registration #: 19731
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Cardinal Health, Inc.

Corporation/Organization Name: Cardinal Health Pharmacy Services, LLC

Mailing Address: 13651 Dublin Ct, 2nd Floor

City: Stafford State: Texas Zip: 77477

Telephone: 281-749-4000 Email: N/A

Contact Person Name: N/A

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the VP, Managed Services (title) for Cardinal Health Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Michael Brown

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/12/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Michael Brown hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the VP, Managed Services (title) for Cardinal Health Pharmacy Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 12 day of January, 20 24

Ginger Ginene Greene
Notary Public

GINGER GINENE GREENE
Notary Public, State of Texas
Comm. Expires 06-26-2027
Notary ID 5939130

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Brown - VP, Managed Services

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 1/12/24

Board Use Only	Date Received: _____	Amount: 500 √#10887462

Nevada State Board of Pharmacy

- **New out-of-Nevada Pharmacy license application**

Cardinal Health Pharmacy Services, LLC
7000 Cardinal Place, Suite 1D
Dublin, OH 43017

Section 12: Application Requirements

Shareholder/Stockholder Information – N/A

This is not relevant for "Cardinal Health Pharmacy Services, LLC" as we are a non-publicly traded company.

Personal History Record Application for Shareholders/Stockholders – N/A

This is not relevant for "Cardinal Health Pharmacy Services, LLC" as we are a non-publicly traded company.

Sterile Compounding Questionnaire – N/A

We will not be providing sterile compounded drugs.

Copy of DEA Registration – N/A

Cardinal Health Pharmacy Services pharmacy is a **non-drug dispensing Pharmacy Service Center** providing remote medication order entry and review for hospitals.
All administration of medications is handled at the client's physical location. Our center does **not** purchase, store, compound, distribute or dispense any pharmaceuticals.

Internet Pharmacy Services Certification – N/A

We will not be providing internet pharmacy services.

Transmit Controlled Substance Prescription Data – N/A

Cardinal Health Pharmacy Services pharmacy is a **non-drug dispensing Pharmacy Service Center** providing remote medication order entry and review for hospitals.
All administration of medications is handled at the client's physical location. Our center does **not** purchase, store, compound, distribute or dispense any pharmaceuticals.

Cardinal Health Pharmacy Services, LLC

Officer & Director List

Name	Title	Business Address	Business Phone #	Work Email Address
Deborah Lynn Weitzman	President	7000 Cardinal Place Dublin, OH 43017	[redacted]	Debbie.Weitzman@cardinalhealth.com
Michael David Brown	Vice President, Managed Services	13651 Dublin Ct Stafford, TX 77477	[redacted]	mike.brown@cardinalhealth.com
Naveen Mansukhani	Director, Pharmacy Operations Management	13651 Dublin Ct Stafford, TX 77477	[redacted] (cell)	naveen.mansukhani@cardinalhealth.com
Brent Mathew Withrow	Assistant Treasurer	7000 Cardinal Place Dublin, OH 43017	[redacted]	brent.withrow@cardinalhealth.com
James William Berkley Gamble	Secretary	13651 Dublin Ct Stafford, TX 77477	[redacted] (cell)	berkley.gamble@cardinalhealth.com
Thomas Deeds	Director of Pharmacy	7000 Cardinal Place Suite 1D Dublin, OH 43017	877-244-5763	thomas.deeds@cardinalhealth.com

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show CARDINAL HEALTH PHARMACY SERVICES, LLC, a Delaware Limited Liability Company, Registration Number 1863596, was registered in the State of Ohio on June 12, 2009, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 17th day of January, A.D. 2024.

Ohio Secretary of State

Validation Number: 202401701484

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 021402400

Cardinal Health Pharmacy Services, Llc

7000 Cardinal Pl Ste 1D
Dublin, OH 43017-1091
Franklin County

Terminal - Pharmacy - LIMITED Category 2

Institutional Pharmacy

June 27, 2022

License 021402400 - Cardinal Health Pharmacy Services, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Chandra Galante
Start 6/27/2022 10:00 AM
End 6/27/2022 11:02 AM

Organization

Name
Cardinal Health Pharmacy Services, Llc

License Type
Terminal - Pharmacy - LIMITED Category 2

Category

License Number
021402400

Business Type
CRP - Contract Remote Order Entry

DEA Number

Responsible Person
Thomas Matthew Deeds, RPH

Hours of Operation
24 hour/7 days

Contact

Address
7000 Cardinal Pl Ste 1D
Dublin, OH 43017-1091
Franklin County

Primary Number
(614) 668-6031

Fax Number
(614) 210-0824

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Thomas Matthew Deeds, RPH		Pharmacist	03223419	[redacted]	

1) Licensing, Responsible Person & DEA Registration

1) Have there been any changes in the pharmacy's ownership, business name or trade name, category, or address without submitting a new application to the Board?

Yes

Observation
This Contract Remote Order Entry Pharmacy is relocating to 7000 Cardinal Place, Suite 1D, Dublin, Ohio. The anticipated move date June 30, 2022.

2) Does the responsible person match what is indicated in eLicense?

Yes

2) Minimum Standards for Institutional Pharmacies

1) Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?

Yes

3) Does the pharmacy have access to the telephone number of a poison control center?

Yes

4) Are all pharmacy staff wearing name tags/badges that include the employee's job title? Warning

Yes

Observation
An employee of a pharmacy must be identified by a name tag that includes the employee's job title.

For pharmacy technicians, the badge must specifically state the technician's registration status (i.e. certified, registered or technician trainee).

*Substantive Change: New rule applies to all pharmacy staff regardless of whether the pharmacy staff is interfacing with the public.

OAC 4729:5-9-02.1

OAC 4729:3-3-03

OAC 4729:3-3-04

OAC 4729:3-3-01

Corrective Action
Discussed New requirement.

5) Are areas where drugs, equipment, and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?

Yes

Observation
This is an address change and the facility was under construction on this date.

3) Personnel

1) Are staff working at the pharmacy properly licensed/registered with the Board?

Yes

Observation
Discussed that biannually and 5 day prior to renewal dates for respective licenses compliance and responsible person verify registrations and licenses.

5) Are certified pharmacy technicians working within their applicable scope of practice?

Yes

Observation
Certified Technicians triage pharmacy calls and assist with customer service issues (if applicable).

4) Positive Identification

1) Has the institutional pharmacy's computerized record keeping system changed since the last inspection?

No

Observation
MOM's is the Cardinal Health computer system. They also have access to approximately 50 Hospital systems as part of their contact for remote order entry.

2) Does the record keeping system capture the positive identification of the pharmacist verifying the prescription information entered into the record keeping system?

Yes

Observation
Discussed requirements. Data Entry, Data Entry Verification, and DUR are required to have positive ID.

3) Does the record keeping system capture the positive identification of the pharmacist conducting a drug utilization review?

Yes

Observation
All pharmacy record keeping systems must capture the positive identification of the pharmacist entering order information into the system.

OAC 4729:5-9-02.3
MOM's and most hospitals use User ID and password, 2-factor app verification, and unique questions. A few pharmacies require manual signature on end of day reports to meet positive ID.

5) Does the record keeping system capture the positive identification of the individual transcribing an order received by telephone, facsimile, or recording device?

Yes

Observation
All pharmacy record keeping systems must capture the positive identification of the individual (pharmacist, pharmacy intern, or certified technician) transcribing an order received by telephone, facsimile, or recording device.

OAC 4729:5-9-02.3

5) Dispensing Records and Patient Profiles

3) Does the pharmacy maintain patient profiles containing the required information?

Yes

Observation
Patient profiles consist of both a patient data record and a drug therapy record.

A patient data record shall contain all the following information:

(1) Full name of the patient for whom the drug is intended.

(2) Patient's date of birth.

(3) Patient's gender, if provided.

(4) A list of current patient-specific data consisting of at least the following, if made known to the pharmacist or agent of the pharmacist:

(a) Drug related allergies;
(b) Previous drug reactions;

(c) History of or active chronic conditions or disease states; and

(d) Other drugs, including nonprescription drugs, devices and nutritional supplements used on a routine basis.

(5) The pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug.

A patient's drug therapy record shall contain all the following information for all prescriptions dispensed by the pharmacy within the last twelve months:

(1) The original medication order.

(2) Date and time of issuance of the medication order by the prescriber.

(3) Full name of the prescriber.

(4) The prescriber's credential (MD/DO, NP, PA, etc.).

(5) Directions for use.

(6) The proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug or device dispensed.

(7) The strength, dosage form, route of administration, and quantity of the drug or device dispensed.

OAC 4729:5-9-02.5

6) Medication Orders & Outpatient Prescriptions

1) Do medication orders contain all the required information?

Yes

Observation
All medication orders for drugs for inpatients shall include the following:

(1) Name of patient;

(2) Name, strength, and dosage form of drug;

(3) Directions for use, including route of administration;

(4) Date prescribed;

(5) The ordering prescriber's positive identification; and

(6) If applicable, the positive identification of the authorized individual transmitting the order on behalf of the prescriber.

OAC 4729:5-9-02.7

9) General Record Keeping Requirements

1) Does the pharmacy's record keeping system contain security features to prevent unauthorized access to the records?

Yes

Observation
All institutional pharmacy records required in accordance with this chapter shall be maintained under appropriate supervision and control to restrict unauthorized access.

This access may include a username and password, security question, pin, fingerprint, etc.

OAC 4729:5-9-02.3

2) Does the pharmacy's record keeping system contain back-up functionality to protect against record loss?

Yes

12) Security, Control, and Storage of Dangerous Drugs and Records

1) Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?

Yes

Observation
The non-dispensing Contract Remote Pharmacy is secured with badge access. Only Pharmacy Personnel will have access. Being that the pharmacy is operated 24 hours a day and a pharmacist is always present, both pharmacy technicians and pharmacist may have badge access.
Discussed having an emergency access badge, tamper evident, and secured in the security office. Responsible Person will perform monthly checks to ensure the emergency badge has not been tampered with.

21) Pharmacist Drug Utilization Review & OARRS

1) Is a pharmacist conducting a prospective drug utilization review for all drugs dispensed?

Yes

Observation
With some exceptions (see below), prior to dispensing any initial medication order or medication order change, a pharmacist shall conduct a prospective drug utilization review of the patient profile for the purpose of identifying the following:

(1) Over-utilization or under-utilization of medications dispensed in the institutional facility;

(2) Therapeutic duplication;

(3) Drug-disease state contraindications;

(4) Drug-drug interactions;

(5) Incorrect drug dosage;

(6) Drug-allergy interactions;

(7) Abuse/misuse;

(8) Inappropriate duration of drug treatment; and

(9) Food-nutritional supplements-drug interactions.

OAC 4729:5-9-02.6

2) Is a pharmacist conducting a retrospective review of medication orders in accordance with the rule?

Yes

Observation
A pharmacist shall conduct a retrospective review of medication orders within a reasonable amount time and make a determination about the safe and appropriate use and the legitimacy of the order in either of the following circumstances:

(1) Any drug removed from the pharmacy or contingency stock in accordance with rule 4729:5-9-03.01 of the Administrative Code; and

(2) The use of override medications.

OAC 4729:5-9-02.6

3) Does the institutional pharmacy/facility have policies and procedures to require pharmacists to report the unsafe or inappropriate prescribing or dosing by prescribers to the appropriate oversight committee?

Yes

Observation
An institutional pharmacy/facility shall develop and implement policies and procedures to require pharmacists to report unsafe or inappropriate prescribing or dosing by prescribers to the appropriate oversight committee.

OAC 4729:5-9-02.6

38) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content. If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection: (1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or (2) An explanation disputing the observed violations. I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner. I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action. Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

Warning

Reviewed by Thomas Matthew Deeds, RPH

(signature)

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2025.

CARDINAL HEALTH PHARMACY SERVICES, LLC

7000 Cardinal Pl Ste 1D
Dublin, OH 43017-1091

License Number: 021402400

Terminal - Pharmacy - LIMITED Category 2

Expiration Date: March 31, 2025

CLASS: Terminal - Pharmacy - LIMITED Category 2
BUSINESS TYPE: CRP – Contract Remote Order Entry

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Thomas Deeds	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Ohio | eLicense Ohio Professional Licensure

License Look Up

1/11/2024 3:46 PM

CARDINAL HEALTH PHARMACY SERVICES, LLC

License Number	021402400
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - LIMITED Category 2
License Issue Date	10/07/2003
License Expiration Date	03/31/2025
License Effective Date	04/01/2023
Street Address	7000 Cardinal Pl Ste 1D
City	Dublin
State	OH
Zipcode	43017-1091
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
Diandra O'Connor	03443633	Pending	Wed Jul 05 00:00:00 GMT 2023	
	03223419	Active	Mon Jun 17 00:00:00 GMT 2013	

Current date & time: **1/11/2024 3:46 PM**

Cardinal Health
13651 Dublin Ct, 2nd Floor
Stafford, TX 77477
281.749.4000 Main Tel.

cardinalhealth.com

CardinalHealth

January 12, 2024

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Suite 206
Reno, NV 89521

Dear Nevada State Board of Pharmacy Representative,

RE: New Out of State Pharmacy License Application / Designated Representative Authorization

As part of the new pharmacy license application process, should an appearance be required at a Nevada board meeting, I, Michael Brown – VP, Managed Services, authorize Thomas Deeds, Director of Pharmacy, to appear as the designated representative on behalf of "Cardinal Health Pharmacy Services, LLC". Included is the Designated Representative Form for Thomas Deeds.

Michael Brown – VP, Managed Services
Name of Authorized Person

Original Signature of Authorized Person — Date 1/12/24

State of Texas, ss. County of Harris

Subscribed and Sworn to before me this 12 day of January, 2024.

Ginger Ginene Greene
Notary Public Signature

GINGER GINENE GREENE
Notary Public, State of Texas
Comm. Expires 06-26-2027
Notary ID 5939130

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Cardinal Health Pharmacy Services, LLC

Pharmacy/Wholesaler License # (if applicable): N/A - new application

Physical Address: 7000 Cardinal Place, Suite 1D

City: Dublin State: Ohio Zip: 43017

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 877-244-5763 Website: N/A

Licensing Company Email: natacha.gomez@cardinalhealth.com

Section 2: Personal Information

First: Thomas Middle: Matthew Last: Deeds

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Scioto Meadows Blvd

City: Grove City State: OH Zip: 43123

Telephon[redacted] Email: thomas.deeds@cardinalhealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520; NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY - MM/YY)	
The Ohio State University		09/93-12/98	
Address	**City**	**State**	**Zip**
281 West Lane Avenue	Columbus	OH	43210
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Dawson-Bryant High School		09/89-05/93	
Address	**City**	**State**	**Zip**
701 High Street	Coal Grove	OH	45638
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/01-01/24	[redacted]Scioto Meadows Blvd	Grove City	OH	43123
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health			08/05-01/24	
Business Address		**City**	**State**	**Zip**
7000 Cardinal Place		Dublin	OH	43017
Phone	**Title**		**Number of Employed Hours**	
877-244-5763	Director of Pharmacy		36,000	

Description of Duties

Oversees pharmacy staff and operations of team. Ensure compliance with state and federal regulations. Training staff on proper processing of medication orders.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/94		OH	Ironton	Lawrence
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Ironton Ohio Police Department		
Reason/Charge				
Criminal Trespassing				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

June of 1994, I was cited for criminal trespassing in Ironton, OH. I and approximately 15 other teenagers were loitering on a CVS parking lot around 11pm. This was a common place for teenagers to gather and "hang out". The Ironton police officers pulled onto the lot and issues each of us a ticket for criminal trespassing ant told us to leave the lot. I paid the fine and did not appear in Court.

Original Signature (electronic, copies or stamps not accepted)

1/12/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/94		OH	Athens	Athens
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Ohio University Police Department		
Reason/Charge				
Disorderly Conduct				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

October of 1994 I was cited for disorderly conduct in Athens, Ohio. I was at the annual Ohio University Halloween party. My friends and I were walking to the downtown area when I picked up and empty beer bottle and said to my friends " here is our reward for walking up the hill" After walking a few steps I set the bottle back down and an Ohio University police officer said that he saw me litter. I explained that I had just picked up the bottle and set it back down a few steps away. He gave me an option to take a $500 ticket for littering or an $85 ticket for disorderly conduct. I took the cheaper ticket, paid the fine and did not appear in court.

Original Signature (electronic, copies or stamps not accepted)

1/12/2024
Date

I, Thomas Deeds, **certify that as the designated representative for**

Cardinal Health Pharmacy Services, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TD TD I am at least 21 years of age;
3. TD TD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TD TD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TD TD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TD TD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TD TD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Thomas Deeds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/12/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Thomas Deeds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/12/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Thomas M Deeds, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/12/2024

Date

Subscribed and Sworn to before me this 12th day of January, 2024

Notary Public Signature

Britannie Miller
Notary Public, State of Ohio
My Commission Expires:
09/16/2028

(Seal)

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail Order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday *	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday *	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays *	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

* On-Call pharmacist available 24/7 via toll free phone number. 24/7 includes holidays and weekends.

Section 1: General Information

Pharmacy Name: CarelonRx Pharmacy, Inc.

Physical Address: 2505 N. Highway 360, Suite 200

City: Grand Prairie State: TX Zip: 75050

Mailing Address (if different from physical address): 5800 Northampton Blvd.

City: Norfolk State: VA Zip: 23502

Telephone: 833-396-0309 Toll Free # (NAC 639.708, NRS 639.23286): 833-396-0309

Fax: 833-310-3762 (licensing only) Contact Email: CarelonRxPharmacyLicensing@carelon.com

Website: _____

Nevada Business License # (if applicable) NV20212034904

Supervising/Managing Pharmacist Name (NRS 639.220): Sarah Lim

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23871

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sarah J. Lim	NV Pharmacist Registration #: 23871
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): CarelonRx Pharmacy, Inc.

Corporation Name: Elevance Health, Inc. (Ultimate Parent Company, incorporated in Indiana)

Mailing Address: 5800 Northampton Blvd.

City: Norfolk State: VA Zip: 23502

Telephone: 833-396-0309 Email: CarelonRxPharmacyLicensing@carelon.com

Contact Person Name: Shelley Smoot

Date of SEC Registration:	SEC Registration Number: 001-16751	Stock Exchange Symbol: ELV

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☒ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Clayton D. Edwards

Print Name of Authorized Person

Clayton D. Edwards

Original signature of Authorized Person (copies or stamps not accepted)

11/13/23

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Clayton D. Edwards hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President (title) for CarelonRx Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Clayton D Edwards
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of November, 2023

Shelley Rae Smoot
Notary Public

SHELLEY RAE SMOOT
NOTARY PUBLIC
REG. #8061916
COMMONWEALTH OF VIRGINIA
MY COMMISSION EXPIRES FEBRUARY 28, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Clayton D. Edwards

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Clayton D Edwards

Original signature of Authorized Person (copies or stamps not accepted)

11/13/23

Date

Board Use Only	Date Received: 2/5/24	Amount: $500 – Check 63133677

carelon Rx | Pharmacy

CARELONRX PHARMACY, INC. OFFICERS AND DIRECTORS

Name	Title	Business Address	Home Address	Phone Numbers & Email	Ownership %	SSN	DOB
Paul E. Marchetti	President, Director	108 Leigus Road Wallingford, CT 06492	[redacted]	(o) 203-677-8708 [redacted] Paul.Marchetti@elevancehealth.com	0%	[redacted]	[redacted]
Clayton D. Edwards	Vice President	376 Northlake Blvd Altamonte Springs, FL 32701		(o) 407-625-6414 [redacted] clayton.edwards@carelon.com	0%		
Vincent E. Scher	Treasurer, Director	220 Virginia Avenue Indianapolis, IN 46204		(o) 317-488-6004 [redacted] Vince.Scher@elevancehealth.com	0%		
Eric K. Noble	Assistant Treasurer	220 Virginia Avenue Indianapolis, IN 46204		(o) 317-488-6538 [redacted] Rick.Noble@elevancehealth.com	0%		
Kathleen S. Kiefer	Secretary	220 Virginia Avenue Indianapolis, IN 46204		(o) 317-488-6562 [redacted] Kathy.Kiefer@elevancehealth.com	0%		
Kirsten C. Hines	Director	220 Virginia Avenue Indianapolis, IN 46204		(o) 253-225-7668 [redacted] Kirsten.Hines@carelon.com	0%		

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Name	Title	Business Address	Federal Tax Identification Number	Ownership %
CarelonRx Pharmacy, Inc.	Owner	4821 North Stone Avenue, Suite C Tucson, AZ 85704	47-3025203	100%
CarelonRx, Inc.	Parent Company of CarelonRx Pharmacy, Inc.	220 Virginia Avenue Indianapolis, IN 46204	82-3062245	100%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Carelonrx Pharmacy, Inc.**, as a FOREIGN CORPORATION (80) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/08/2021, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/02/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202402024321836
You may verify this certificate online at http://www.nvsos.gov

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CARELONRX PHARMACY, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF JUNE, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5688829 8300

SR# 202326S1295

Authentication: 203472796

Date: 06-02-23

You may verify this certificate online at corp.delaware.gov/authver.shtml

carelon Rx | Pharmacy

Elevance Health, Inc. Major Stockholders

As of today's date, the following are the largest four stockholders of Elevance Health, Inc.:

1. The Vanguard Group, Inc. – holds 8.74% of Outstanding Shares
2. Vanguard Group, Inc. (Subfiler) – holds 8.61% of Outstanding Shares
3. T. Rowe Price Group, Inc. – holds 4.97% of Outstanding Shares
4. State Street Corporation – holds 4.44% of Outstanding Shares

2022

This certifies that the pharmacy named below is hereby licensed to operate as a Class **G** pharmacy.

License No. **34750** Expiration Date: **6/30/2025**

Balances: **0**

CARELONRX PHARMACY INC
2505 N HWY 360 STE 200
GRAND PRAIRIE TX 75050

Julie R. Spier

Julie R. Spier, R.Ph.
President

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 34750

CARELONRX PHARMACY INC

License Information

License Status Active
License # 34750
Expiration Date 06/30/2025
Date License Issued 06/06/2023

Address

2505 N HWY 360 STE 200
GRAND PRAIRIE, TX 75050
County DALLAS
Phone (833) 396-0309

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Central Processing Pharmacy
Type of Ownership Corporation
Type of Pharmacy Community Multi
# of Hospital beds

Employment Information

Pharmacist in Charge
ALCOCER, GABRIEL

Pharmacy Profile ¥

Accessible to disabled persons? Yes

Participates in the Texas Medicaid program? No

Translating services (Listed Below if Available)

Spanish
Telecomm. for the deaf (TDD)
American Sign Language

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	No
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	Yes

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
ABDULRUB, SAMEY HASSAN	68558	06/10/2021	08/31/2025	Staff	Active
ACEVEDO, JERMAN	63577	09/20/2018	06/30/2024	Staff	Active
AJIBOLA, OLABISI	36925	05/14/1997	09/30/2025	Staff	Active

ALCOCER, GABRIEL	47917	08/28/2009	02/29/2024	PIC	Active
ALHEETI, NOOR ADEL	71360	09/22/2022	04/30/2024	Staff	Active
ANOWAI, OBINNA	69139	08/17/2021	11/30/2025	Consultant	Active
ARAI, KATHY T	59534	09/22/2016	02/28/2025	Staff	Active
ASAMOAH, ROBERT KUMAH	51793	07/30/2012	08/31/2025	Staff	Active
BHAKTA, RADHIKA DHARMESH	67449	08/27/2020	07/31/2024	Staff	Active
BOYD, MONICA JEANETTA	50651	08/29/2011	04/30/2024	Staff	Active
BROOKS, EVAN CHERRELLE	67963	11/19/2020	04/30/2025	Staff	Active
BROWN, NEKEIDRA CHANTAY	44819	10/19/2006	11/30/2024	Staff	Active
FOFIE, LORETTA BIENIH	56313	03/26/2015	06/30/2025	Staff	Active
GRIFFIN, MELINDA RENE	31569	02/12/1990	06/30/2025	Staff	Active
HABEEB, RAEESA	68033	12/10/2020	04/30/2025	Staff	Active
HALL, PRESTON ADAMS	49148	08/05/2010	07/31/2024	Staff	Active
HINGWE, MEGHANA VINOD	58565	06/30/2016	10/31/2024	Staff	Active
KENNEDY, CYRILLA MARIE	36396	08/08/1996	05/31/2024	Staff	Active
KENNEDY, ROBERT STEVEN	63887	11/01/2018	01/31/2025	Staff	Active
LIEU, HUONG	57173	08/13/2015	10/31/2025	Staff	Active

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Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ALHEETI, OLA	300754	09/24/2019	09/30/2024	Staff	Active
ALI, SAEED M.	358971	08/15/2023	08/31/2025	Staff	Active
ANDERSON, EBONI NICOLE	154110	10/21/2009	09/30/2025	Staff	Active
ANDRAE, EMILEIGH	352921	03/27/2023	03/31/2025	Staff	Active
BAKER, AMANDA MERCEDES SORIA	221024	07/08/2013	08/31/2025	Staff	Active
BEDOY, GRISEL	225645	12/13/2013	09/30/2024	Staff	Active
BLEVINS, NICOLE	227523	02/06/2014	11/30/2024	Staff	Active
BOLDON, MIAJA	324784	07/26/2021	06/30/2025	Staff	Active
CASTANEDA, PERLA	228663	03/13/2014	09/30/2024	Staff	Active
CASTILLO, IVONNE	269792	05/02/2017	02/28/2025	Staff	Active
COFFEY, CHLOE MORGAN	307129	04/07/2020	04/30/2024	Staff	Active
DE LA CRUZ HERRERA, ANDRES	307856	05/11/2020	05/31/2024	Staff	Active
DELEON, RACHEL LEE	101368	04/24/2004	04/30/2025	Staff	Active
DHELA, RAYE MECHELLE	352159	03/06/2023	03/31/2025	Staff	Active
DIXON, JENNIFER	233675	08/12/2014	07/31/2024	Staff	Active
DORSETT, JASMINE	247208	09/16/2015	09/30/2025	Staff	Active
FERRIS, JULIA MICHELLE	112953	07/29/2004	01/31/2025	Staff	Active
FRAIRE, JUAN	222968	09/06/2013	05/31/2024	Staff	Active
FULLER, SIMONE	345993	10/06/2022	10/31/2024	Staff	Active
GEORGIOU, DONIA	284826	06/26/2018	01/31/2026	Staff	Active

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Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
CARELONRX, INC.	OWNER	220 VIRGINIA AVENUE,	INDIANAPOLIS	IN	46204
KIEFER, KATHLEEN S	OFFICER	,			
EDWARDS, CLAYTON DAVID	OFFICER	,			
SCHER, VINCENT EDWARD	OFFICER	,			
NOBLE, ERIC KENNETH	OFFICER	,			
MARCHETTI, PAUL EDWARD	OFFICER	,			

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Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Notice of Inspection

Facility Information

Name: *CARELONRX PHARMACY INC*

License Number: *34750*

Address: *2505 N HWY 360 STE 200, GRAND PRAIRIE, TX 75050*

Phone: *(833) 396-0309*

Email:

Class of License: *G*

License Expiration: *06/30/2025*

DEA #: *N/A*

DEA Expiration:

Inspection Information

Type: *Compliance*

Purpose: *Licensee Request*

Date: *01/17/2024*

Arrival Time: *9:00 AM*

Acknowledgment

This is to acknowledge that Texas State Board of Pharmacy Agent has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I have read the Notice of Inspection and understand its contents and purpose;
2. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
3. I have had the purpose of the entry into the above-described facility by the Boards agent stated to me; and
4. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Gabriel Alcocer *Pharmacist In Charge* *47917*

Witness

Isaac Gonzalez

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *CARELONRX PHARMACY INC* License Number: *34750*

Class of License: *G*

Inspection Information

Type: *Compliance* Purpose: *Licensee Request*

Date: *01/17/2024* Arrival Time: *9:00 AM* Departure Time: *10:30 AM*

Action Taken: *Inspection*

General Comments: *Licensed in IL,UT,AZ,WY and MT.*

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*

Comment

Advised to publicly display pharmacy license and/or PIC's wall certificate or renewaL

09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?)	*Satisfactory*
34. Notifications	*Satisfactory*
76. PIC (Does the pharmacy have a pharmacist-in-charge?)	*Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean	*Satisfactory*
05. Equipment Inspection	*Satisfactory*
07. Security	*Satisfactory*
08. Environment	*Satisfactory*

Library

06. Required Library	*Satisfactory*

Training

60. Documentation of required training	*Satisfactory*
61. Supervision of supportive personnel	*Satisfactory*

Patient/Computer/Dispensing Records

18. Records available	*Satisfactory*
22. Data processing system compliance	*Satisfactory*
82. Patient Medication Records	*Satisfactory*
84. Drug regimen review	*Satisfactory*

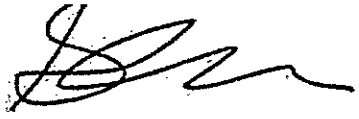
Policies & Procedures/SOPs

70. Required policies & procedures/SOPs	*Satisfactory*
87. Quality Control/Assurance	*Satisfactory*

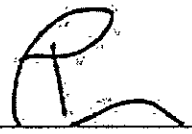
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Gabriel Alcocer



Isaac Gonzalez

Pharmacist in Charge Attestation:

I hereby attest the following statements are true and accurate (initial each statement below):

_____ I am the Pharmacist-in-Charge (PIC) **of** *CARELONRX PHARMACY INC*, pharmacy license number *34750*, and I ☑ was/ ☐ was not present during a Compliance Inspection conducted by a Texas State Board of Pharmacy Compliance Officer/Inspector on *01/17/2024*.

_____ I received and reviewed the Notice of Inspection, Inspection Report, and Warning Notice (if applicable) issued by the Compliance Officer/Inspector.

_____ I reviewed the document titled Texas State Board of Pharmacy "Red Flags" Checklist for Pharmacies YOU MIGHT BE A PILL MILL IF.

_____ If applicable, the Warning Notice issued contains *0* deficiencies which may require corrections to resolve. I affirm that each of the deficiencies will be corrected by the date noted on the Warning Notice.

_____ I was present and completed this Attestation during the Compliance Inspection.

If not completed during the Compliance Inspection, please email this completed form to the TSBP Compliance Inspector for your area or to inspections@pharmacy.texas.gov within 7 days of the date of the inspection.

Signed: _____ **Date:** *01/17/2024*

Printed Name: *Gabriel Alcocer* **License No.(if applicable):** *47917*

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: mail order	☒ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, S, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Nomi Pharma LLC dba Nomi Health Pharmacy

Physical Address: 1435 S 4800 W Suite 100

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 385-375-6555 Toll Free # (NAC 639.708, NRS 639.23286): 833-745-3200

Fax: 385-375-6563 Contact Email: nomipharma-ut@nomihealth.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Justin Bryner

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21982

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Paisley Lusk	NV Pharmacist Registration #: 23342 ✓
Name: Justin Bryner	NV Pharmacist Registration #: 21982 ✓
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Nomi Health Inc

Corporation/Organization Name: Nomi Pharma LLC

Mailing Address: 898 N 1200 W Ste 201

City: Orem State: UT Zip: 84057

Telephone: 3853756555 Email: nomipharma-ut@nomihealth.com

Contact Person Name: Justin Bryner

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☑ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Sr Director, Pharmacy Operations (title) for Nomi Health Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Justin Bryner

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

12/30/2022

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Justin Bryner hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Sr Director, Pharmacy Operations (title) for Nomi Health Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 6th day of Jan, 2023

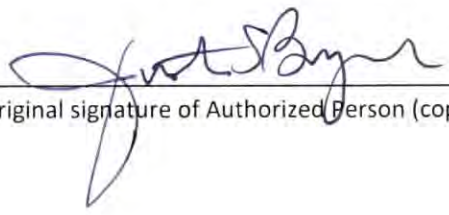
Notary Public

STEVEN BRIGHAM AGUILAR
Notary Public - State of Utah
Comm. No. 720508
My Commission Expires on
Sep 14, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Bryner

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

12/30/2022

Date

Board Use Only	Date Received: _____	Amount: 500.00 CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nomi Pharma LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1435 S 4800 W Ste 100

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 385-375-6555 Website: n/a

Licensing Company Email: nomipharma-ut@nomihealth.com

Section 2: Personal Information

First: Justin Middle: Scott Last: Bryner

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] S Pheasant View Dr

City: Draper State: UT Zip: 84020

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern Nevada		08/06-06/09	
Address	**City**	**State**	**Zip**
10920 S River Front Pkwy	South Jordan	UT	84095
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
University of Utah		08/00-05/05	
Address	**City**	**State**	**Zip**
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
Bachelors of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Brighton High School			
Address	**City**	**State**	**Zip**
2220 Bengal Blvd	Cottonwood Heights	UT	84121
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/09-current	[redacted]S Pheasant View Dr	Draper	UT	84020
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Nomi Pharma LLC			01/22-01/23
Business Address	**City**	**State**	**Zip**
1435 S 4800 W Ste 100	Salt Lake City	UT	84104
Phone	**Title**		**Number of Employed Hours**
385-375-6555	Sr Director, Pharmacy Operations		2080
Description of Duties			
Oversee all pharmacy operations and pharmacy services			

Business Name			From - To (MM/YY – MM/YY)
Magellan Rx			04/17-01/22
Business Address	**City**	**State**	**Zip**
2256 S 3600 W	Salt Lake City	UT	84119
Phone	**Title**		**Number of Employed Hours**
800-424-5878	Director, Clinical Pharmacy Operations		10000
Description of Duties			
Oversee pharmacy operations for Specialty and Mail order pharmacies			

Business Name			From - To (MM/YY – MM/YY)
VRx byMail			04/16-04/17
Business Address	**City**	**State**	**Zip**
2256 S 3600 W	Salt Lake City	UT	84119
Phone	**Title**		**Number of Employed Hours**
855-271-4810	Manager, Pharmacy Operations		2080
Description of Duties			
Manager and Pharmacist in Charge			

Business Name			From - To (MM/YY – MM/YY)
Costco Wholesale			07/09-current
Business Address	**City**	**State**	**Zip**
11100 South Auto Mall Dr	Sandy	UT	84070
Phone	**Title**		**Number of Employed Hours**
801-790-0001	Pharmacist		15000
Description of Duties			
Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Justin Bryner **, certify that as the designated representative for**

Nomi Pharma LLC ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JSB I am at least 21 years of age;
3. JSB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JSB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JSB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JSB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JSB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bryner, Justin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/06/20023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Bryner

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

01/06/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, JUSTIN BRYNER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/23/23

Date

Subscribed and Sworn to before me this 23 day of Jan, 2023

Notary Public Signature

HELEN YOUNG
Notary Public - State of Utah
Comm. No. 725604
My Commission Expires on
Jul 5, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Nomi Pharma LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 3696 West 2100 South

City: Salt Lake City State: UT Zip: 84120

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 385-375-6555 Website: n/a

Licensing Company Email: nomipharma-ut@nomihealth.com

Section 2: Personal Information

First: Mark Middle: Last: Newman

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN[redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]ry Canyon Drive

City: Lindon State: Utah Zip: 84042

Telephone[redacted] Email[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Utah		08/08 - 05/09	
Address	City	State	Zip
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
M.S., Finance			

School Name		From - To (MM/YY – MM/YY)	
Westminster University		09/02 - 12/04	
Address	City	State	Zip
1840 South 1300 East	Salt Lake City	UT	84105
Diploma/Degree obtained, if any			
B.A., International Business			

School Name		From - To (MM/YY – MM/YY)	
Brighton High School		08/99 - 06/02	
Address	City	State	Zip
2220 East Bengal Blvd	Cottonwood Heights	UT	84121
Diploma/Degree obtained, if any			
High School diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - present	[redacted]Dry Canyon Drive	Lindon	UT	84042
2009 - 05/19	[redacted] East 30 South	Orem	UT	84058

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Nomi Health, Inc.			03/19 - Present	
Business Address	**City**	**State**	**Zip**	
898 N 1200 W	Orem	UT	84057	
Phone	**Title**			
801-232-7432	Founder, CEO			
Description of Duties				
Drive to solve the employee healthcare crisis in a market based way. Drive to eliminate the middleman in healthcare across insurance, billing, collections, pharmacy, EOBs.				

Business Name			From - To (MM/YY – MM/YY)	
Roster Inc.			09/17 - Present	
Business Address	**City**	**State**	**Zip**	
2701 N Thanksgiving Way	Lehi	UT	84043	
Phone	**Title**			
801-232-7432	Investor and Board Member			
Description of Duties				
Investor and board member of Roster where they provide an all-in-one-platform that simplifies and streamlines managing multiple ambassador programs, from creators to athletes and super fans.				

Business Name			From - To (MM/YY – MM/YY)	
Nectar HR			08/17 - Present	
Business Address	**City**	**State**	**Zip**	
815 W 1250 S	Orem	UT	84058	
Phone	**Title**			
385-213-0195	Investor and Board Member			
Description of Duties				
Investor and board member of Nectar HR where they provide employee recognition software.				

Business Name			From - To (MM/YY – MM/YY)	
Liam June Ventures			06/17 - Present	
Business Address	**City**	**State**	**Zip**	
94 Dry Canyon Drive	Lindon	UT	84042	
Phone	**Title**			
801-232-7432	Investor			
Description of Duties				
Investment management and family office				

Business Name			From - To (MM/YY – MM/YY)	
HireVue, Inc.			07/04 - 05/17	
Business Address	**City**	**State**	**Zip**	
10876 South River Front Pkwy	South Jordan	UT	84095	
Phone	**Title**			
801-316-2910	CEO, Founder			
Description of Duties				
Led all teams with HireVue's offering of a web-based video interview system that lets recruiters and hiring managers see video clips of job candidates before an in person interview answering their questions that they enter in the system.				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Nomi Health is involved in litigation on a variety of matters in the ordinary course of business, but none that will interfere with Nomi's ability to conduct its business on a day to day basis.

At HireVue, there was a shareholder dispute that was handled by its insurance carriers and ultimately settled by the parties during Mark's tenure at HireVue; however, he no longer has access to that documentation.

Original Signature (electronic, copies or stamps not accepted)

9-14-23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Newman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-14-23

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Mark Newman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-14-23

Date

Subscribed and Sworn to before me this 14th day of September, 2023

Amanda Godfrey

Notary Public Signature

AMANDA J. GODFREY
NOTARY PUBLIC - STATE OF UTAH
My Commission Expires January 27, 2027
COMMISSION NUMBER 729037

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Nomi Pharma LLC

Pharmacy/MDEG/Wholesaler License # (if applicable):

Physical Address: 3696 West 2100 South

City: Salt Lake City State: UT Zip: 84120

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 385-375-6555 Website: n/a

Licensing Company Email: nomipharma-ut@nomihealth.com

Section 2: Personal Information

First: Loren Middle: Last: Larsen

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] East 1600 North

City: Orem State: UT Zip: 84057

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Clemson University		08/93 - 05/95	
Address	**City**	**State**	**Zip**
201 Sikes Hall	Clemson	SC	29630
Diploma/Degree obtained, if any			
M.S., Computer Science			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		09/89 - 06/93	
Address	**City**	**State**	**Zip**
201 Presidents Circle	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
B.S., Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Skyline High School		09/87 - 06/89	
Address	**City**	**State**	**Zip**
3251 East 3760 South	Salt Lake City	UT	84109
Diploma/Degree obtained, if any			
Did not graduate			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19 - present	[redacted]E 1600 N	Orem	UT	84057
12/06 - 10/19	[redacted]East 490 North	Lindon	UT	84042

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Videra Health			12/20 - Present
Business Address	**City**	**State**	**Zip**
898 N 1200 W	Orem	UT	84057
Phone	**Title**		
	CEO, Founder		

Description of Duties

Responsible for funding and financial operation of the business, responsible for overall company and product strategy, and have the marketing, sales, customer experience and product/engineering teams reporting through me

Business Name			From - To (MM/YY – MM/YY)
Nomi Health, Inc.			03/19 - present
Business Address	**City**	**State**	**Zip**
898 N 1200 W	Orem	UT	84057
Phone	**Title**		
801-471-8828	Board Member		

Description of Duties

Attend regular board meetings and advise on matters submitted to the board by the company

Business Name			From - To (MM/YY – MM/YY)
HireVue, Inc.			04/11 - 11/20
Business Address	**City**	**State**	**Zip**
10876 South River Front Pkwy	South Jordan	UT	84095
Phone	**Title**		
801-316-2910	CTO		

Description of Duties

Member of executive leadership team, responsible for product strategy and delivery and operation of product for customers, responsible for overall budget and staffing of teams, and executive responsible for Corporate IT, etc.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Nomi Health is involved in litigation on a variety of matters in the ordinary course of business, but none that will interfere with Nomi's ability to conduct its business on a day to day basis.

At HireVue, there was a shareholder dispute that was handled by its insurance carriers and ultimately settled by the parties during Loren's tenure at HireVue; however, he no longer has access to that documentation.

Loren Larsen

Original Signature (electronic, copies or stamps not accepted)

9/14/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LOREN LARSEN
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/14/2023
Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, [redacted] Loren Larsen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

09/14/2023
Date

Subscribed and Sworn to before me this 14TH day of September, 2023

Notary Public Signature

AMANDA J. GODFREY
NOTARY PUBLIC - STATE OF UTAH
My Commission Expires January 22, 2027
COMMISSION NUMBER 720837

(Seal)

UTAH DEPARTMENT OF COMMERCE
Division of Professional Licensing

160 E 300 S
P.O. Box 16741
Salt Lake City, UT 84114-6741

Phone: (801) 530-6628
Toll Free: (866) 275-3675
Online: DOPL.utah.gov
Email: DOPLInvestigations@utah.gov

CLASS A
RETAIL
PHARMACY

INSPECTION

☑ Opening ☐ Random

INFORMATION

Pharmacy Name: Nomi Pharma LLC Date: 8/30/2023

License Number: 13485459-1703 Exp Date: 01/10/2024

C.S. License Number: 13485459-8913 Exp Date: 01/10/2024

DEA Registration: FN1271201e Exp Date: 10/31/2024

Pharmacy FEIN Number (Tax ID): 87-4094440

Pharmacy Email: nomipharma-UT@nomihealth.com

Pharmacy Phone Number: 385-375-6555 Fax: 385-375-6563

Pharmacy Toll Free Number: 833-745-3200

Affiliated Websites: www.nomihealth.com

Pharmacy Hours: Monday-Friday: 9AM-5PM Saturday: Closed Sunday: Closed

Pharmacy Address: 3696 W 2100 S

City: Salt Lake City State: Utah Zip: 84120

Pharmacist In Charge (PIC): Paisley Lusk

PIC License Number: 8785327-1701 Expiration Date: 9/30/2025

Personnel

List ALL pharmacists, interns, pharmacy technicians and techs-in-training (attach a separate sheet, if necessary):

Name: See attached. License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

Name: License # Exp:

CLASS A RETAIL PHARMACY INSPECTION

Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:
Name:	License #	Exp:

INSPECTION

	YES	NO	
1	☒	☐	The facility shall maintain a current list of licensed employees involved in the practice of the pharmacy at the facility. The list shall include individual licensee names, license classifications, license numbers, and license expiration dates. The list shall be readily retrievable. The list may be maintained in paper or electronic form. [UAC R156-17b-614a (5)(a)(i-vi)(b)]
2	☒	☐	Notification has been provided to the Division in regards to the unique email address used for self audits or pharmacy alerts. The pharmacy will notify the division of any change in the email address within seven days of the change. [UAC R156-17b-603 (2) and (3) (t) (i-ii)]
3	☒	☐	Notification has been provided to the Division in regards to the assignment of the PIC at the above stated pharmacy. The Division is notified of a change in PIC within 30 days of the change. [UAC R156-17b-603 (3) (s)]
4	☐	☐	If the facility has a pharmacy technician training program, the program and curriculum of education and training, meets standards established by Division rule made in collaboration with the Board. [UAC R156-17b-303a (3)] ☒ N/A
5	☒	☐	A pharmacy technician trainee shall practice only under the direct supervision of a pharmacist, and in a ratio not to exceed one pharmacy technician trainee to one pharmacist or two pharmacy technician trainees to one pharmacist, if a licensed pharmacy technician or intern is working during the same shift. [UAC R156-17b-601(4)(a)(i-ii)]
6	☒	☐	A licensed pharmacy technician shall practice under the general supervision of a licensed pharmacist. [UCA 58-17b-102 (57)]
7	☒	☐	A pharmacy technician may administer vaccines and emergency medications pursuant to delegation by a pharmacist... And is under "direct", on-site supervision by the delegating pharmacist as defined in R156-1-102a(4)(a); [UAC R156-17b-601 (3)(b)]
8	☒	☐	The operating standards for a Pharmacist acting as a preceptor includes meeting the following criteria by providing direct, on-site supervision to no more than two pharmacy interns during a working shift. [UAC R156-17b-606(3)(a)]
9	☐	☐	In accordance with Subsecton 58-17b-102(72)(b) all supportive personnel shall be under the supervision of a licensed pharmacist or DMP. The licensed pharmacist or DMP shall be present in the area where the person being supervised is performing services and shall be immediately available to assist the person being supervised in the serivces being performed expect for the delivery of pre-filled prescriptions as provided in Subsection (1)(g) above. [UAC R156-17b-607 (3)] N/A
10	☐	☐	In accordance with Subsection 58-17b-102(72)(a), supportive personnel may assist in any tasks not related to drug preparation or processing, including: [UAC R156-17b-607 (1)(a-g)] N/A

- ☐ stock ordering and restocking;
- ☐ cashiering;
- ☐ billing;

☐ filing;
☐ receiving a written prescription and delivering it to the pharmacist, pharmacy intern, pharmacy technician, pharmacy technician trainee, DMP, or DMP designee;
☐ housekeeping;
☐ delivering a pre-filled prescription to a patient.

11 ☒ ☐ The pharmacist-in-charge (PIC) is responsible for assuring that no pharmacy or pharmacist operates the pharmacy or allows operation of the pharmacy with a ratio of pharmacist to pharmacy personnel which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. [UAC R156-17b-603 (3) (r)]

12 ☒ ☐ All individuals employed in a pharmacy facility having any contact with the public or patients receiving services from that pharmacy facility does wear on their person a clearly visible and readable identification showing the individual's name and position. [UCA 58-17b-603 (1)]

13 ☒ ☐ When communicating by any means, written, verbal, or electronic, pharmacy personnel do identify themselves as to licensure classification. [UCA 58-17b-603 (2)]

14 ☒ ☐ The facility or parent company shall maintain a record for not less than five years of the initials or identification codes that identify each dispensing pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified; therefore identical initials or identification codes shall not be used. [UAC R156-17b-614a (8)]

15 ☒ ☐ The facility does have current and retrievable editions of the following reference publications in print or electronic format and readily available and retrievable to facility personnel: [UAC R156-17b-614a (4) (a-k)]

- ☒ UCA 58-1 (DOPL Licensing Act)
- ☒ UCA 58-17b (Pharmacy Practice Act)
- ☒ UCA 58-37 (Controlled Substance Act)
- ☒ UCA 58-37f (Controlled Substance Database Act)
- ☒ Code of Federal Regulations Title 21 parts 1300 to end
- ☒ General Drug References
- ☒ UAC R156-1 (General Rules of DOPL)
- ☒ UAC R156-17b (Pharmacy Practice Act Rules)
- ☒ UAC R156-37 (Controlled Substance Act Rules)
- ☒ UAC R156-37f (Controlled Substance Database Act Rule)
- ☐ FDA Approved Drug Product (Orange Book)

16 ☒ ☐ The facility is well lighted, ventilated, clean and sanitary. [UAC R156-17b-614a (1) (a)]

17 ☒ ☐ If transferring a drug from a manufacturer's or distributor's original container to another container, the dispensing area, shall have a sink with hot and cold culinary water separate and apart from restroom facilities. All required equipment shall be clean and in good operating condition. [UAC R156-17b-614a (1) (b)]

18 ☒ ☐ The facility is equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory. [UAC R156-17b-614a (1) (c)]

19 ☒ ☐ The facility is equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility. [UAC R156-17b-614a (1) (e)]

20 ☒ ☐ All out of date legend drugs and controlled substances shall be removed from the inventory at regular intervals and in correlation to the beyond use date imprinted on the label. [UAC R156-17b-605(1)]

CLASS A RETAIL PHARMACY INSPECTION

21 ☒ ☐ The facility is stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare. [UAC R156-17b-614a (1) (f)]

22 ☒ ☐ If dispensing controlled substances, the facility is equipped with a security system to permit detection of entry at all times when the facility is closed, and provide notice of unauthorized entry to an individual, and be equipped with a lock on any entrances to the facility where drugs are stored. [UAC R156-17b-614a (1)(g)(i-ii)(h)(i-ii)]

23 ☒ ☐ If the pharmacy does not store drugs in a locked cabinet and has a drop/false ceiling, the pharmacy's perimeter walls shall extend to the hard deck, or other measures shall be taken to prevent unauthorized entry into the pharmacy. [UAC R156-17b-614a (15)] ☐ N/A

24 ☒ ☐ Only a licensed Utah pharmacist or authorized pharmacy personnel does have access to the pharmacy when the pharmacy is closed. [UAC R156-17b-614a (7)]

25 ☒ ☐ A pharmacy shall not dispense a prescription drug or device to a patient unless a pharmacist is physically present and immediately available in the facility. [UAC R156- 17b-614a (6)]

26 ☒ ☐ The temperature of the pharmacy is maintained within a range compatible with the proper storage of the drugs. [UAC R156-17b-614a (3)]

27 ☒ ☐ The temperature of the refrigerator and freezer is maintained within a range compatible with the proper storage of drugs requiring refrigeration or freezing. The pharmacy shall keep a daily written or electronic log of the temperature of the refrigerator or freezer on days of operation. The pharmacy shall retain the log for three years. [UAC R156-17b-614a (3)]

28 ☒ ☐ For the purpose of promoting therapeutic appropriateness, a pharmacist shall at the time of dispensing a prescription, or a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant conditions, situations or items, such as: [UAC R156-17b-611 (2) (a-g)]

- ☒ Inappropriate drug utilization
- ☒ Drug-disease contraindications
- ☒ Incorrect drug dosage
- ☒ Drug-allergy interactions
- ☒ Therapeutic duplications
- ☒ Drug-drug interactions
- ☒ Incorrect duration of drug treatment
- ☒ Clinical abuse or misuse

29 ☒ ☐ Facility does have a counseling area to allow for confidential patient counseling. [UAC R156-17b-614a (1)(i)]

30 ☒ ☐ Every pharmacy shall verbally offer to counsel a patient or a patient's agent in a personal face-to-face discussion regarding each prescription drug dispensed. If the patient or patient's agent delivers the prescription in person to the pharmacist or pharmacy intern; or receives the drug in person at the time it is dispensed at the facility. [UCA 58-17b-613 (1)]

31 ☐ ☐ A pharmacist or pharmacy intern that receives a prescription from a patient by means other than personal delivery, and that dispenses prescription drugs to the patient by means other than personal delivery shall provide patient counseling to a patient regarding each prescription drug the pharmacy dispenses and provide each patient with a toll-free telephone number by which the patient can contact the pharmacist or pharmacy intern at the pharmacy for counseling. [UCA 58-17b-613(2)]

N/A

32 ☐ ☐ If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable: [UCA R156-17b-610(6)(a-c)

N/A

☐ the pharmacy shall provide the information specified in R156-17b-610(3) be delivered with the dispensed prescription in writing.

☐ if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."

☐ written information provided in Subsection (b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

33 ☒ ☐ The offer to counsel is documented and said documentation shall be available to the Division. These records must be maintained for a period of five years and be available for inspection within 7-10 business days. [UAC R156-17b-610 (4)]

34 ☒ ☐ A pharmacy may only deliver a prescription drug to a patient or patient's agent in person at the pharmacy or via the United States Postal Service, a licensed common carrier, or supportive personnel, if the pharmacy takes reasonable precautions to ensure the prescription drug is delivered to the patient or patient's agent or returned to the pharmacy. [UCA 58-17b-602(9)(a)(b)(i-ii)]

35 ☒ ☐ A pharmacy that employs the United States Postal Service or other common carrier to deliver a filled prescription directly to a patient shall, under the direction of the PIC, or other responsible employee: [UAC R156-17b-608(1)(a-e)(2)(a-c)]

☒ Use adequate storage or shipping containers and shipping processes to ensure drug stability and potency. The shipping processes shall include the use of appropriate packing material and devices, according to the recommendations of the manufacturer or the United States Pharmacopeia Chapter 1079, in order to ensure that the drug is kept at appropriate storage temperatures throughout the delivery process to maintain the integrity of the medication.

☒ Use shipping containers that are sealed in a manner to detect evidence of opening or tampering.

☒ Develop and implement policies and procedures to ensure accountability, safe delivery, and compliance with temperature requirements. The policies and procedures shall address when drugs do not arrive at their destination in a timely manner or when there is evidence that the integrity of a drug was compromised during shipment. In these instances, the pharmacy shall make provisions for the replacement of the drug.

☒ Provide for an electronic, telephonic, or written communication mechanism for a pharmacy to offer counseling to the patient as defined in section 58-17b-613; and provide documentation of such counseling.

☒ Provide information to the patient indicating what the patient should do if the integrity of the package or drug was compromised during shipment.

36 ☒ ☐ Each drug dispensed from the pharmacy does have a label securely affixed to the container indicating the required minimum information, including: [UCA 58-17b-602 (5) (a) (i-viii)]

☒ name, address, & phone number of pharmacy
☒ filling date or last dispensing date
☒ name of the prescriber
☒ trade, generic or chemical name
(Unless Otherwise Indicated by Prescriber)
☒ serial number of prescription
☒ name of the patient or animal owner/species
☒ directions for use & cautionary statements
☒ amount dispensed & strength of dosage form
☒ beyond use date

37 ☒ ☐ Unless otherwise requested, child-resistant containers are used for dispensing medications to patients. [UAC R156-17b-502(6) & 16 CFR 1700.14]

38 ☒ ☐ Controlled substances are not accepted back for destruction unless allowed for by state and federal law. [UAC R156-37-606 (1-2) & 21 CFR 1307.21]

CLASS A RETAIL PHARMACY INSPECTION

39 ☒ ☐ The registered pharmacy only processes electronically signed prescriptions for controlled substances under the following conditions: the pharmacy uses a pharmacy application that meets all the applicable requirements; the prescription is otherwise in conformity with the requirements of the Code of Federal Regulations; and Certification Authority (CA) has been obtained. The electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form and at no time may the prescription be converted to another form *(i.e. facsimile)* for transmission. [CFR, Title 21, Chapter 11, Section 1311, UAC R156-17b-613 (1)]

40 ☒ ☐ Prescription files, including refill information, is maintained for a minimum of five years and should be immediately retrievable in written or electronic format. [UAC R156-17b-612 (4)]

41 ☒ ☐ Prescription records may be maintained electronically so long as the original of each prescription, including telephone prescriptions, is maintained in a physical file and contains all of the information required by federal and state law; and an automated data processing system is used for the storage and immediate retrieval of refill information for prescription orders. [UAC R156-37-602 (4) (a-b)]

42 ☐ ☐ N/A All records relating to Schedule II controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3) (5)]

43 ☒ ☐ All records relating to Schedule III, IV, V controlled substances received, purchased, administered or dispensed by the practitioner shall be maintained separately from all other records of the pharmacy or practice. Records shall be maintained by the licensee for a period of five years. [UAC R156-37-602(3) (6)]

44 ☒ ☐ Requirement for annual controlled substances inventory shall be within 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems. [UAC R156-17b-605 (4)]

45 ☒ ☐ Requirements for taking the initial controlled substances inventory shall include the following: all pharmacies shall take an inventory on the opening day of business. Such inventory shall include all controlled substances including any out-of-date drugs and drugs in automated pharmacy systems. In the event a pharmacy commences business with no controlled substances on hand, the pharmacy shall record this fact as the initial inventory. An inventory reporting no Schedule I and II controlled substances shall be listed separately from an inventory reporting no Schedule III, IV, and V controlled substances. The initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (4) of this section. [UAC R156-17b-605 (3) (a-c)] ☐ N/A

46 ☒ ☐ General Requirements for inventory of a pharmacy shall include: [UAC R156-17b-605 (2)(a)(b)(c)(f)(g)(h)(k)(l)]

- ☒ the PIC shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;
- ☒ the inventory records shall be maintained for a period of five years and be readily available for inspection
- ☒ the inventory records shall be filed separately from all other records
- ☒ the inventory may be taken either as the opening of the business or the close of business on the inventory date;
- ☒ the person taking the inventory and the PIC shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the PIC and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory.

☑ the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances;

☑ if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventories, the perpetual inventory shall be reconciled on the date of the inventory.

47	☐	☐ N/A	All pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances that shall be reconciled according to facility policy. [UAC R156-17b-605(6)]
48	☐	☐ N/A	The pharmacy does reconcile its controlled substance inventory to account for shortages of controlled substances. [UAC R156-17b-603 (3) (k) & R156-37-502(4)]
49	☑	☐	Any facility who experiences any theft, including diversion, or significant loss of controlled substances shall immediately file the appropriate forms with the Drug Enforcement Administration, with a copy to the Division directed to the attention of the Investigation Bureau Division; and report the incident to the local law enforcement agency. [UAC R156-37-602 (2)]
50	☑	☐	Pharmacists or other responsible individuals do verify that the suppliers' invoices of controlled substances, listed on the invoices were actually received by clearly recording their initials and the actual date of receipt of the controlled substances. [UAC R156-17b-614a (11)]
51	☑	☐	The facility shall maintain a record of suppliers' credit memos for controlled substances. [UAC R156-17b-614a (12)]
52	☑	☐	The facility does maintain a copy 3 of DEA order form (form 222) which has been properly dated, initialed, and filed and all copies of each unaccepted or defective order form and any attached statements or other documents. [UAC R156-17b-614a(9)(a-c)]
53	☑	☐	The Division shall implement on a statewide basis, including non-resident pharmacies as defined in Section 58-17b-102, the following two options for a pharmacist to submit information: real-time submission of the information required to be submitted under this part of the controlled substance database; and 24-hour daily or next business day, whichever is later, batch submission of the information required to be submitted under this part to the controlled substance database. [UCA 58-37f-203(1)(a)(i,ii)]
54	☑	☐	In accordance with 58-37f-203(6), the pharmacist-in-charge and the pharmacist identified in Subsections 58-37f-203(2) and (3) shall provide the following data fields to the Division: the state that issued identification, type of identification used, identification number used and first and last name of individual picking up dispensed drug. [UCA R156-37f-203 (4) (bb-ff)]
55	☐	☑	The pharmacy maintains emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMT's, ambulances)? If the answer is "yes", note name(s) of facilities or entities.
56	☐	☑	The pharmacy maintains automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home? If the answer is "yes", note type and location.
57	☐	☑	The pharmacy utilizes an Automated Pharmacy System? If the answer is "yes" to this question, a automation questionnaire must be completed. [UAC R156-17b-620]
58	☐	☑	The facility is engaged in hazardous drug compounding as defined by USP-NF Chapter 800. If you answer "yes" to this question, a compounding questionnaire must be completed.
59	☐	☑	The facility is engaged in simple, medium, or complex compounding activities as defined by USP 35 Chapter 795. If you answer "yes" to this question, a compounding questionnaire must be completed. [(UAC R156-17b-614a (2)]
60	☐	☑	The facility is engaged in low, medium, or high risk *sterile* compounding as defined by USP 35 Chapter 797. If you answer "yes" to this question, a compounding questionnaire must be completed. [UAC R156-17b-614a (2)]

COMMENTS

- Assisted by PIC Paisley Lusk & Staff pharmacist Justin Bryner.
- A current list of licensed employees was readily available
- The pharmacy does not have support personnel.
- All pharmacy personnel wore name tags & identify by licensure classification when communicating on the phone.
- No out-of-date medications were found in the pharmacy stock.
- Temperature logs are kept digitally & manually- all logs inspected were compliant.
- The pharmacy does not deliver prescription medications
- The pharmacy mails prescriptions all requirements are compliant.
- Labels include all required information.
- The pharmacy does not currently have CII medications. a zero inventory was conducted
- Controlled substance inventory for CIII-CV was compliant.
- Controlled substance invoices are all dated & signed.

- The pharmacy does not have an automated pharmacy system or engage in compounding.

☑ By checking this box it is indicated that the undersigned Division Investigator has reviewed the above inspection report and comments made with the undersigned "Responsible Party."

Signature of Responsible Party: Paisley Lnok Date: 8/30/23

Name of Responsible Party (Print): Paisley Lnok

Signature of Division Investigator: Date: 8/30/23

Name of Division Investigator (Print): Kaila Silcox

Revised 8/2023

Michael L. Parson
Governor
State of Missouri

Sheila Solon, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Missouri Department of
Commerce & Insurance
Chlora Lindley-Myers, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard P.O. Box 625
Jefferson City, MO 65109
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
MissouriBOP@pr.mo.gov
pr.mo.gov/pharmacists

This is to certify that the records of the Missouri Division of Professional Registration indicate the following information regarding Nomi Pharma, LLC.

LICENSE TYPE:	Drug Distributor
LICENSE NUMBER:	2023013171
DATE ISSUED:	4/7/2023
STATUS:	Renewal Sent/No Payment
EXPIRATION DATE:	10/31/2023
CURRENT DISCIPLINARY ACTION:	None
PAST DISCIPLINARY ACTION:	

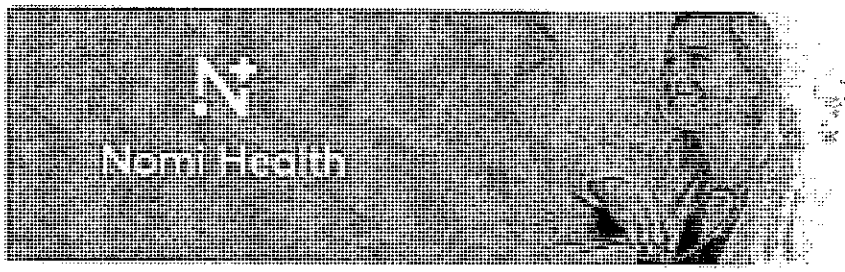
Mary Blue

Missouri Board of Pharmacy

7/18/23

Date

This is the only form that will be used by the Missouri Board of Pharmacy for the purpose of license verification.



Rewiring our healthcare system, together.

Board of Pharmacy,

Nomi Health Pharmacy (Nomi Pharma LLC) is a wholly owned subsidiary of Nomi Health INC. Nomi Health INC is a privately owned company. There are three individuals with greater than 5% ownership of the company. Those individuals are Mark Newman, Josh Walker and Loren Larsen. Collectively they own 58% of Nomi.

The remaining equity (42%) of the company is owned by over 600 stakeholders.

Nomi Pharma LLC Officer list and business addresses

Joshua Walker, President
1435 S 4800 W Ste 100, Salt Lake City, UT 84104
[redacted]

Mark Singleton, Vice President
1435 S 4800 W Ste 100, Salt Lake City, UT 84104
[redacted]

Dan Schwendiman, Secretary/Treasurer
1435 S 4800 W Ste 100, Salt Lake City, UT 84104
[redacted]

Utah Department of Commerce
Division of Corporations & Commercial Code
160 East 300 South, 2nd Floor, PO Box 146705
Salt Lake City, UT 84114-6705
Service Center: (801) 530-4849
Toll Free: (877) 526-3994 Utah Residents
Fax: (801) 530-6438
Web Site: http://www.commerce.utah.gov

01/10/2023
12621797-016101102023-1354311

CERTIFICATE OF EXISTENCE

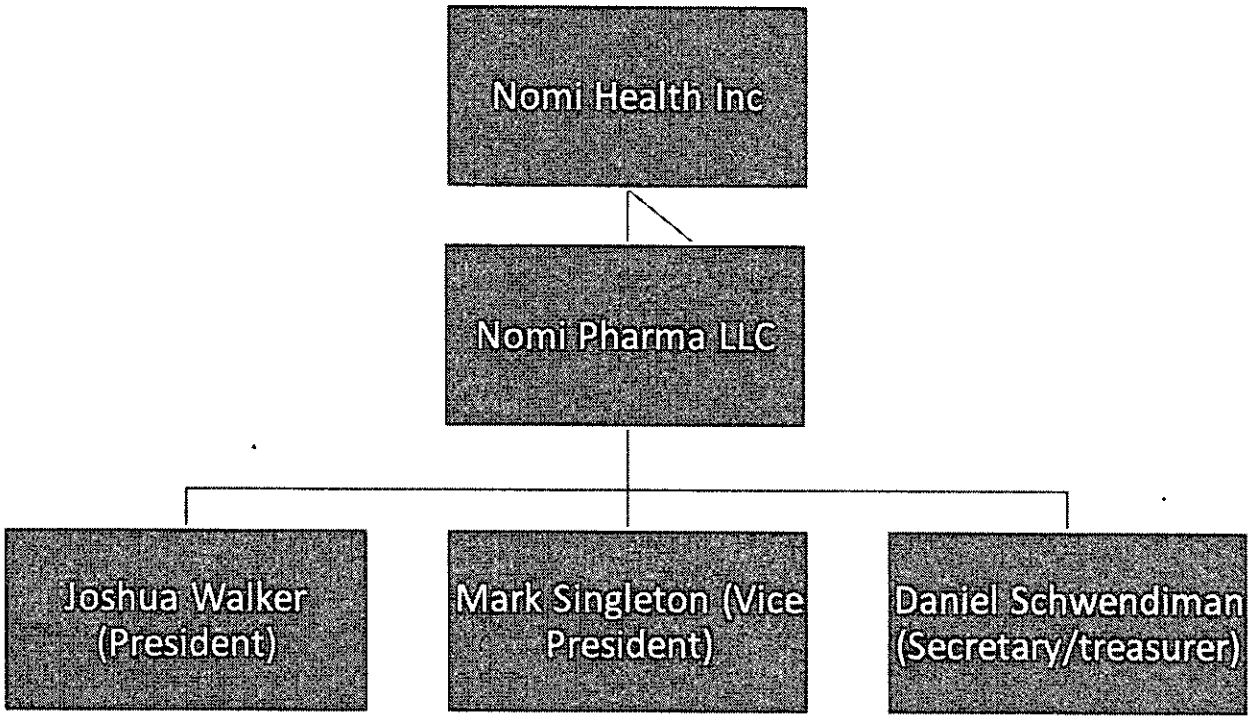
Registration Number:	12621797-0161
Business Name:	NOMI PHARMA LLC
Registered Date:	December 22, 2021
Entity Type:	LLC - Foreign
Status:	Current

The Division of Corporations and Commercial Code of the State of Utah, custodian of the records of business registrations, certifies that the business entity on this certificate is authorized to transact business and was duly registered under the laws of the State of Utah. The Division also certifies that this entity has paid all fees and penalties owed to this state; its most recent annual report has been filed by the Division **(unless Delinquent)**; and, that Articles of Dissolution have not been filed.

L. Veillette

Leigh Veillette
Director
Division of Corporations and Commercial Code

Corporate Business Structure



Nomi Pharma LLC is a wholly owned subsidiary of Nomi Health Inc. Nomi Health INC is a privately owned company. There are three individuals with greater than 5% ownership of the company. Those individuals are Mark Newman (37.8014%), Loren Larsen (14.0196%) and Joshua Walker (6.179%). Collectively the three own 58% of Nomi Health Inc. The remaining equity (42%) of the company is owned by over 600 stakeholders.

Joshua Walker (President), Mark Singleton (Vice President), and Daniel Schwendiman (Secretary/Treasurer) are the designated officers for Nomi Pharma LLC

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Norco Inc.

Physical Address: 400 Main St., Suite 105

City: Boise State: ID Zip: 83702

Mailing Address (if different from physical address): 1125 W Amity Rd

City: Boise State: ID Zip: 83705

Telephone: 844-819-4907 Toll Free # (NAC 639.708, NRS 639.23286): 844-819-4907

Fax: 833-726-1971 Contact Email: jeffn@norco-inc.com

Website: www.norco-inc.com

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Jeffrey Nielsen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23708

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Jeffrey Nielsen	NV Pharmacist Registration #: 23708
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name: n/a	Credentials:	%:
Name: n/a	Credentials:	%:
Name: n/a	Credentials:	%:
Name: n/a	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Idaho

Parent Company (if any): n/a

Corporation/Organization Name: Norco Inc.

Mailing Address: 1125 W. Amity Rd

City: Boise State: ID Zip: 83705

Telephone: 208-336-1643 Email: compliance@norco-inc.com

Contact Person Name: Roger Hudgens

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Director of Risk Management (title) for Norco Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Roger Hudgens

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/19/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Roger Hudgens hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Director of Risk Management (title) for Norco Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19th day of September, 2023

Julie F. Thomas
Notary Public

JULIE F THOMAS
Comm. No. 29477
NOTARY PUBLIC
Expires: 07/08/2025
STATE OF IDAHO

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger Hudgens

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/5/2024

Date

Board Use Only	Date Received: _____	Amount: 500 V# 710363

Norco
WELDING • SAFETY • MEDICAL
Supplies and Gases
1125
WEST AMITY ROAD
BOISE, ID
83705

THE JOINT COMMISSION ACCREDITED
ISO 9001-2015 - TÜV CERTIFIED
QUALITY SYSTEM REGISTERED

(208) 336-1643 •TEL
(208) 433-6160 •FAX

TO: Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Case No. 21-176-MP-N

Norco acknowledges the lack of the proper MDEG license with regards to furnishing medical oxygen at our 740 Fairgrounds Rd location in Winnemucca Nevada prior to the Notice from the Nevada State Board of Pharmacy in November of 2021. Norco has a long history of providing medical gases in the Northwest and is aware of the importance of proper licensure and quality measures with regards to medical oxygen. Regarding the missing licensure for our Winnemucca location, this was purely an oversite on Norco's part. Norco prides itself on being a responsible member of the communities we operate in and as such we intend to secure the proper licensure and abide by the Board's rules regarding medical oxygen.

Once the notice was received, Norco immediately complied with the cease-and-desist order and halted all medical oxygen sales from our Winnemucca location. Norco has applied for the required MDEG licensure to meet with Nevada State Board of Pharmacy requirements. Additionally, through this process, it was determined that Norco should apply for a Wholesale license at our Winnemucca location, in addition to the MDEG licensure noted in the cease-and-desist order. This Wholesale application is also being submitted for approval.

Norco, sincerely regrets the oversight that led to the lack of proper licensure at our Winnemucca NV location and looks forward to working with the Nevada State Board of Pharmacy to ensure compliance with licensure requirements and continue to serve the needs of the Winnemucca community and healthcare providers.

Sincerely,

Roger Hudgens
Director of Risk Management, Norco Inc.

FILED
JUL 13 2022
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NORCO, INC.,** **License No. MP00047,** **Respondent.**	**CASE NO. 21-176-MP-N** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Norco, Inc., License No. MP00047, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about May 11, 2022, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about June 9, 2022, Respondent filed an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives the rights to a

hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Respondent is licensed to operate and engage in the business of furnishing medical devices in Nevada at 440 30th Street in Elko;

B. On or about November 2, 2021, Respondent was served with notice pursuant to NRS 639.2895 to cease and desist engaging in the business of furnishing medical devices in Nevada, specifically medical oxygen, from a second location at 740 Fairgrounds Road in Winnemucca without a license; and

C. By engaging in the business of furnishing medical devices in Nevada from 740 Fairgrounds Road in Winnemucca, Respondent and/or Respondent's employees violated NRS 639.233(1), NRS 639.288, NAC 639.6942(2) and/or NAC 639.6944(1), and engaged in unprofessional conduct as defined in NAC 639.6941(1)(a) and NAC 639.945(1)(i), (j) and (k).

8. Respondent timely complied with the November 2, 2021, cease and desist order and immediately applied for a medical products provider license for the location at 740 Fairgrounds Road in Winnemucca.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Norco, Inc., License No. MP00047, shall:

A. Pay a fine of Five Thousand Dollars ($5000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order; and

B. Pay Five Hundred Dollars ($500.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on July 13, 2022. Respondent or his counsel may appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts

set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 28 **day of June, 2022**

Roger Hudgens, Director of Risk Management

NORCO, INC.,
License No. MP00047

Signed this 30th **day of June, 2022**

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Norco, Inc., License No. MP00047, in Case No. 21-176-MP-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 31st day of July, 2022.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 15th day of July 2022, I served a true and correct copy of the foregoing document by Certified U.S. Mail to the following:

Norco Industrial
740 Fairgrounds Rd.
Winnemucca, NV 89445

KRISTOPHER MANGOSING

Idaho State Board of Pharmacy

1199 Shoreline Ln., Suite 303 | P.O. Box 83720 | Boise, Idaho 83720-0067
Telephone (208) 334-2356 | FAX (208) 334-3536 | www.idaho.gov/bop

April 5, 2013

JEFFREY NIELSEN PHARM D
C/O WALGREEN PHARMACY
265 S EAGLE RD
EAGLE ID 83616

Dear Dr. Nielsen,

Enclosed find a copy of the Stipulation and Consent Order that was executed by Board Chairman Berk Fraser on April 4, 2013. The Order became effective as of the date of execution and thus, you are required to abide by all terms contained in the enclosed Order. This is a legal document and it is recommended you keep a copy for future reference.

You are required by this Order to pay the Board of Pharmacy $500.00 in administrative fines within 180 days of this Order, October 4, 2013. The fine can be paid by check or money order payable to the Board of Pharmacy. Also indicated, you must complete 6 credits of Continuing Pharmacy Education pertaining to prescription and/or medication error, within 90 days of the date of this Order; evidence of completion must be submitted to the Board office no later than July 4, 2013.

If you have any questions regarding this matter, please feel free to contact me.

Sincerely,

Mark Johnston, R.Ph.
Executive Director

Enc: Order BOP 13-030

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the License and Registration of:	)	Case No. BOP-13-029
JEFFREY NIELSEN, Pharm D Pharmacist License No. P6098, CS Registration No. CS12256,	)	**STIPULATION AND CONSENT ORDER**
Respondent.	)	

WHEREAS, information has been received by the Idaho State Board of Pharmacy ("Board") that constitutes sufficient grounds for the initiation of an administrative action against Jeffrey Nielsen, Pharm D ("Respondent"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

1. The Board regulates the practice of pharmacy in the State of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the State of Idaho.

2. Respondent is a licensee of the Board and holds Pharmacist License No. P6098 ("License") and Controlled Substance Registration No. CS12256 ("Registration"). Respondent's License and Registration are subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, and the Board's rules promulgated at IDAPA 27.01.01, *et seq.*

///

///

B. STIPULATED FACTS

1. On August 20, 2012, Respondent filled a prescription for canine Patient S.F. at the Walgreens Pharmacy in Eagle, Idaho. Patient S.F.'s prescription was written for 64.8 mg Phenobarbital tablets. Respondent, however, filled Patient S.F.'s prescription with 15 mg Phenobarbital tablets, which resulted in Patient S.F. receiving approximately ¼ the dose he was supposed to receive. Respondent was responsible for overseeing and ensuring Patient S.F.'s prescription was filled correctly. As a result of the misfill, Patient S.F. suffered repeated seizures and eventually had to be sedated.

2. While Respondent's error was unintentional, Respondent acknowledges his actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondent admits to violating the following statutes and rules:

a. Idaho Code § 54-1726(a) (a pharmacist shall not engage in unprofessional conduct as defined by Board rule);

b. IDAPA 27.01.01.500.06 (unprofessional conduct includes failing to strictly follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents or labeling); and

c. Idaho Code § 54-1726(f) (being found by the board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter.

3. Respondent, in lieu of proceeding with a formal disciplinary hearing, hereby agrees the Board may enter a final order against his license and registration as set forth in Section C below.

C. STIPULATED PENALTIES

1. It is agreed that Respondent shall pay to the Board an administrative fine in the amount of five hundred and No/100 Dollars ($500.00) within one hundred eighty (180) days of the effective date of this Order.

2. Respondent shall complete six (6) credits of continuing education pertaining to prescription or medication error. Respondent shall complete these continuing education credits, and provide proof of completion to the Board, no later than ninety (90) days after the effective date of this Order. This continuing education requirement is in addition to the annual continuing education requirements necessary to maintain a pharmacist license in the State Idaho.

3. All costs associated with Respondent's compliance with the terms of this Stipulation are the sole responsibility of Respondent.

D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondent waives his ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondent has violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file a Motion to Enforce, or other administrative complaint, setting forth the allegations of non-compliance and notifying Respondent, and his attorney, if applicable, that Respondent may request a hearing regarding the allegations of non-compliance. If Respondent does not request a hearing pursuant to the Motion to Enforce, or other administrative complaint, any allegations of non-compliance will be deemed admitted.

2. If Respondent fails to comply with this Stipulation, Respondent's license and registration may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be the sole responsibility of Respondent.

E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

I, Jeffrey Nielsen, by affixing my signature hereto, acknowledge the following:

1. I have read and admit to the foregoing allegations stated above in section B. I understand these allegations constitute cause for disciplinary terms upon my license and registration. I agree the Board has jurisdiction to proceed in this matter with my consent as indicated by my signature hereto.

2. I have read the above Stipulation fully and have had the opportunity to discuss it with legal counsel. I understand that by its terms I am waiving certain rights provided to me under Idaho law.

3. I understand I have, among others, the right to: a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify myself; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. I hereby freely and voluntarily waive these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

4. I understand that in signing this Stipulation I am enabling the Board to impose disciplinary terms upon my license and registration, as set forth in Section C, without further process.

5. I understand the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. I understand that, if approved as proposed, the Board will issue an Order on this Stipulation according to the aforementioned terms, and I hereby agree to the above Stipulation for settlement. I understand that if the Board approves this Stipulation subject to changes, and those changes are acceptable to me, the Stipulation will take effect and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable to me or the Board rejects this Stipulation, this Stipulation will be of no effect and admissions in this Stipulation and negotiations

preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing.

6. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted by me, I waive any right I may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation.

7. I understand the Board shall have the right to make full disclosure of this Stipulation and subsequent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

8. I understand this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

9. This Stipulation contains the entire agreement between the parties, and Respondent is not relying on any other agreement or representation of any kind, verbal or otherwise.

10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director for the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly scheduled meeting of the Board.

11. Except for Paragraph E.6., which becomes effective when Respondent signs this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board and a Board member signs the attached Order.

DATED this 28th day of February, 2013.

Jeffrey Nielsen, Pharm D
Respondent

I recommend the Board enter an Order based upon this Stipulation.

DATED this 4 day of March, 2013.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

Colleen D. Zahn
Deputy Attorney General

I recommend the Board enter an Order based upon this Stipulation.

DATED this 4 day of April, 2013.

Mark Johnston, Executive Director
Idaho State Board of Pharmacy

ORDER

Pursuant to Idaho Code § 54-1728 and § 37-2718, the foregoing is adopted as the decision of the Idaho State Board of Pharmacy in this matter and shall be effective on the 4 day of April, 2013. **IT IS SO ORDERED.**

IDAHO STATE BOARD
OF PHARMACY

By
Berk Fraser, R.Ph.
Board Chair

CERTIFICATE OF MAILING

I HEREBY CERTIFY that on this 5th day of April, 2013, I caused to be served a true and correct copy of the foregoing STIPULATION AND CONSENT ORDER addressed to:

Jeffrey Nielsen
c/o Walgreen's Pharmacy
265 S. Eagle Road
Eagle, Idaho 83616

- [x] U.S. Mail
- [ ] Hand Delivery
- [x] Certified Mail, Return Receipt Requested
- [ ] Overnight Mail
- [ ] Facsimile:

Colleen D. Zahn
Deputy Attorney General
P.O. Box 83720
Boise, ID 83720-0010

- [ ] U.S. Mail
- [ ] Hand Delivery
- [ ] Certified Mail, Return Receipt Requested
- [ ] Facsimile:
- [x] Email: colleen.zahn@ag.idaho.gov
  reta.massano@ag.idaho.gov

Mark Johnston, Executive Director

2089

Licensee Details

This is a primary source verification website offered by the Idaho State Board of Pharmacy.

Demographic Information

Facility Name: Norco Inc

Ownership Type: agency1prof0ownershipType-255

Physical Address

Street Address: 400 Main St Ste 105 **Fax:** **Phone:** 8448194907

City: Boise **Zip:** 83702 **State:** ID

County: Ada **Country:** United States

License Information

DBA: Norco Inc

Lic #: RDO71768 **Type:** Resident Drug Outlet

Status: Active **Orig. Issued Date:** 7/25/2023 **Expiry:** 12/31/2024 **Effective:** 7/25/2023

Status Reason: License Issuance **Status Date:** 7/25/2023 **Renewed:** 12/5/2023

Method: Application

Disciplinary Action

Disciplinary Action is indicated above in red, if the section is BLANK no action exists for this record.

Board Orders

No Related Documents

STATE OF IDAHO

Phil McGrane | Secretary of State
Business Office
450 North 4th Street
PO Box 83720
Boise, ID 83720

September 12, 2023

Request Type: Certificate of Existence/Filing
Request #: 0005399679
Receipt #: 000876374

Issuance Date: 09/12/2023
Copies Requested: 0

Regarding: **NORCO, INC.**
Filing Type: General Business Corporation (D)
Formation/Qualification Date: 12/29/1967
Status: Active-Good Standing
Duration Term: Perpetual

File # : 129650
Formation Locale: IDAHO
Inactive Date:

Certificate of Existence

I, Phil McGrane, Secretary of State of the State of Idaho, do hereby certify that effective as of the issuance date noted above

NORCO, INC.

is a Corporation duly incorporated under the law of this State with a date of incorporation and duration as given above.

Phil McGrane
Idaho Secretary of State

Processed By: Business Division

Verification #: 025278633

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSES
DOPL

BRAD LITTLE
Governor
RUSSELL BARRON
Administrator

State of Idaho
Division Of Occupational and Professional Licenses
Board of Pharmacy

11341 W Chinden Blvd.
P.O. Box 83720
Boise, ID 83720-0063
(208) 334-3233 • dopl.idaho.gov

FACILITY
Norco Inc
400 W Main St Ste 105
Boise, ID 83702
8448194907

LICENSE
License No: RDO71768
License Type: Resirug Outlet

Inspection Type:	Initial	**Inspection Date:**	7/14/2023
Result:	Pass		

Notes:
Remarks: location in Meridian is still active and move to this location will take place once insurance contracts are updated. No controlled substances, though DEA is carried.

Checklist Results

24.36.01.103. BOARD INSPECTIONS AND INVESTIGATIONS

Question	Answer
24.36.01.103.02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction.	True
24.36.01.230.01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration,	True

24.36.01.300. DRUG OUTLETS: MINIMUM FACILITY STAND

Question	Answer
24.36.01.300.01. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA.	Compliant
24.36.01.300.02. Controlled Substance Storage. Drug outlets that dispense prescription drugs must store controlled substances in accordance with federal law.	Compliant
24.36.01.300.03. Authorized Access to the Restricted Drug Storage Area. Access to the restricted drug storage area must be limited to authorized personnel.	Compliant
24.36.01.300.05. Electronic Recordkeeping System. A drug outlet that dispenses more than twenty (20) prescriptions per day must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. The electronic recordkeeping system must have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes.	Compliant

24.36.01.406. LABELING STANDARDS

Question	Answer
24.36.01.406. LABELING STANDARDS. All prescription drugs must be in an appropriate container and bear information that identifies the drug product, any additional components as appropriate, and the individual responsible for its final preparation. 01. Standard Prescription Drug. A prescription drug for outpatient dispensing must be labeled in accordance with federal law.	Compliant

24.36.01.500. RECORDKEEPING: MAINTENANCE AND INVEN

Question	Answer
24.36.01.500.01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction.	Compliant
24.36.01.500.07. Electronic Records Storage. Records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format.	Compliant
24.36.01.303.03. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law.	Not Applicable

24.36.01.700. COMPOUNDING DRUG PREPARATIONS.

Question	Answer
24.36.01.700.02.c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use.	Not Applicable
24.36.01.700.05. Drug Compounding Controls. a. Policies and Procedures. In consideration of the applicable provisions of USP Chapter 795 concerning pharmacy compounding of non-sterile preparations, USP Chapter 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed:	Not Applicable

24.36.01.701. STERILE PREPARATION.

Question	Answer
24.36.01.230.08. Sterile Preparation Endorsement. A drug outlet engaged in sterile preparation must obtain a single endorsement for one (1) or more hood or aseptic environmental control devices.	Not Applicable
24.36.01.701.04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile preparations in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions.	Not Applicable
24.36.01.701.05. Sterile Preparation Equipment. A drug outlet in which sterile preparations are prepared must be equipped with at least the following: a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless written documentation can be provided from the aseptic isolator manufacturer that any component of garbing is not necessary; b. A sink; c. A refrigerator for proper storage of additives and finished sterile preparations prior to delivery when necessary; and d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet, or a comparable compounding area when authorized by USP Chapter 797.	Not Applicable
24.36.01.701.07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical preparations and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including:	Not Applicable

24.36.01.702. HAZARDOUS DRUGS PREPARATION

Question	Answer
24.36.01.702.01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants.	Not Applicable
24.36.01.702.02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs.	Not Applicable
24.36.01.702.05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal.	Not Applicable
24.36.01.702.06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit-of-use packaging.	Not Applicable
24.36.01.702.09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule.	Not Applicable

24.36.01.103.03. Inspection Deficiencies.

Question	Answer
24.36.01.103.03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection	Not Answered
Remote Dispensing Reviewed	No
24.36.01.103.04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. [Discussed with]	Jeff
Disclaimer - Any items not discussed specifically by compliance officer on this inspection does not constitute compliance nor approval.	True

THE UNDERSIGNED LICENSEE OR REPRESENTATIVE AT THE TIME OF INSPECTION ACKNOWLEDGES RECEIPT OF THIS INSPECTION REPORT.

7/14/2023

Amy Hickerson, Compliance Officer | Date | Signature of Owner/Representative

Norco
WELDING • SAFETY • MEDICAL
Supplies and Gases
1125
WEST AMITY ROAD
BOISE, ID
83705

THE JOINT COMMISSION ACCREDITED
ISO 9001-2015 - TÜV CERTIFIED
QUALITY SYSTEM REGISTERED

(208) 336-1643 •TEL
(208) 433-6160 •FAX

Norco Inc.
Corporate Ownership / Officers

Norco Inc. – Ownership:

Ownership Entity	Trustee	Ownership %
Metolius Trust	Nicole Kissler	19.62%
McKenzie Trust	Cheryl Larabee	33.25%
Deschutes Trust	Cheryl Larabee	12.14%
Norco ESOP Trust	Alerus Financial	35.0%

Norco Inc. – Executive Officers:

Roger Hudgens
Director of Risk Management
Norco, Inc.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Norco Inc

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 400 W Main St, Suite 105

City: Boise State: ID Zip: 83702

Mailing Address (if different from physical address): 1125 W Amity Rd

City: Boise State: ID Zip: 83705

Telephone: 844-819-4907 Website: www.norco-inc.com

Licensing Company Email: compliance@norco-inc.com

Section 2: Personal Information

First: Jeffrey Middle: A Last: Nielsen

Alias(es, nicknames, name changes, etc.): Jeff

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]N Brooklet pl

City: Boise State: ID Zip: 83713

Telephone: [redacted] Email: jeffn@norco-inc.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129).	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Idaho State University			08/03 - 05/07
Address	**City**	**State**	**Zip**
921 South 8th Avenue, Stop 8288	Pocatello	ID	83209
Diploma/Degree obtained, if any			
Doctorate of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Boise State Univeristy			08/00-05/03
Address	**City**	**State**	**Zip**
1910 W University Dr	Boise	ID	83725
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Meridian High School			08/92-05/96
Address	**City**	**State**	**Zip**
1900 W Pine Ave	Meridian	ID	83642
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/09-present	[redacted]N Brooklet Pl	Boise	ID	83713
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy			01/15-present	
Business Address		**City**	**State**	**Zip**
795 W Overland Rd		Meridian	ID	83642
Phone	**Title**		**Number of Employed Hours**	
208-917-6905	Staff Pharmacist		13,000	
Description of Duties				
Assist pharmacy manager with operation of retail pharmacy (verifying prescriptions / order/prescription/vaccine record retention)				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens Pharmacy			06/07-12/14	
Business Address		**City**	**State**	**Zip**
265 S Eagle Rd		Eagle	ID	83616
Phone	**Title**		**Number of Employed Hours**	
208-319-0543	Pharmacy Manager		15,000	
Description of Duties				
Oversee operations of retail pharmacy / scheduling / managing staff / record retention				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Jeffrey A Nielsen, **certify that as the designated representative for**

Norco Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. jan I am at least 21 years of age;
3. jan I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. jan I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. jan I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. jan I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. jan I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jeffrey Nielsen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/14/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Nielsen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/14/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Ada

I, Jeffrey Nielsen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/14/23

Date

Subscribed and Sworn to before me this 14 day of Sept 2023

Notary Public Signature

DAWN R. SCHOENECKER
Comm. No. 36727
NOTARY PUBLIC
Expires: 09/20/2025
STATE OF IDAHO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Norco Inc.

Pharmacy/MDEG/Wholesaler License # (if applicable): n/a

Physical Address: 400 Main St. Ste 105

City: Boise State: ID Zip: 83702

Mailing Address (if different from physical address): 1125 W. Amity Rd.

City: Boise State: ID Zip: 83705

Telephone: 775-623-2200 Website: www.norco-inc.com

Licensing Company Email: compliance@norco-inc.com

Section 2: Personal Information

First: Cheryl Middle: Ann Last: Larabee

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted]W. Thornberry Drive

City: Boise State: ID Zip: 83702

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Golden State University		09/79 - 09/80	
Address	City	State	Zip
536 Mission St.	San Francisco	CA	94105
Diploma/Degree obtained, if any			
M.B.A.			

School Name		From - To (MM/YY – MM/YY)	
Moorhead State College		09/71 - 05/75	
Address	City	State	Zip
1104 7th Ave S.	Moorhead	MN	56563
Diploma/Degree obtained, if any			
B.A.			

School Name		From - To (MM/YY – MM/YY)	
Osseo High School		09/68 - 05/71	
Address	City	State	Zip
317 2nd Ave NW	Osseo	MN	56369
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12 - Current	[redacted] Thornberry Dr.	Boise	ID	83702
05/98 - 05/12	[redacted] Parkside Dr.	Boise	ID	83712
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
McKenzie Trust			09/08 - Current	
Business Address	**City**		**State**	**Zip**
313 Thornberry Dr.	Boise		ID	83702
Phone	**Title**			
208-863-4223	Trustee			
Description of Duties				
Fiduciary				

Business Name			From - To (MM/YY – MM/YY)	
Deschutes Trust			01/21 - Current	
Business Address	**City**		**State**	**Zip**
313 Thornberry Dr.	Boise		ID	83702
Phone	**Title**			
208-863-4223	Trustee			
Description of Duties				
Fiduciary				

Business Name			From - To (MM/YY – MM/YY)	
Norco Inc.			01/10 - Current	
Business Address	**City**		**State**	**Zip**
1125 W. Amity Rd.	Boise		ID	83705
Phone	**Title**			
208-336-1643	Director			
Description of Duties				
Board of Directors/Company Oversight				

Business Name			From - To (MM/YY – MM/YY)	
Boise State University			01/05 - 07/20	
Business Address	**City**		**State**	**Zip**
1910 University Dr.	Boise		ID	83725
Phone	**Title**			
208-426-1000	AVP, Professor			
Description of Duties				
AVP Advancement, Professor				

Business Name			From - To (MM/YY – MM/YY)	
ZAGG Inc.			09/13 - 02/22	
Business Address	**City**		**State**	**Zip**
910 Legacy Center Way	Salt Lake City		UT	84047
Phone	**Title**			
801-263-0699	Director			
Description of Duties				
Board of Directors/Company Oversight				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cheryl Larabee

Print Name (First, Last)

Cheryl Larabee — 7-11-23

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Ada

I, Cheryl Larabee, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cheryl Larabee — 7-11-23

Original Signature — **Date**

Subscribed and Sworn to before me this 11th day of July 2023.

Julie F. Thomas

Notary Public Signature

JULIE F THOMAS Comm. No. 29477 NOTARY PUBLIC Expires: 07/08/2025 STATE OF IDAHO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Norco Inc.

Pharmacy/MDEG/Wholesaler License # (if applicable): n/a

Physical Address: 400 Main St. Ste 105

City: Boise State: ID Zip: 83702

Mailing Address (if different from physical address): 1125 W. Amity Rd.

City: Boise State: ID Zip: 83705

Telephone: 775-623-2200 Website: www.norco-inc.com

Licensing Company Email: compliance@norco-inc.com

Section 2: Personal Information

First: Nicole Middle: Celeste Last: Kissler

Alias(es, nicknames, name changes, etc.): n/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: [redacted] W. Amity Rd.

City: Boise State: ID Zip: 83705

Telephone: [redacted] Email: nicolek@norco-inc.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Oregon State University		09/03 - 06/07	
Address	City	State	Zip
1500 SW Jefferson Way	Corvallis	OR	97331
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Boise High School		08/00 - 05-03	
Address	City	State	Zip
1010 W. Washington St.	Boise	ID	83702
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/20 - Current	[redacted] Sendero Ln	Boise	ID	83712
01/14 - 07/20	[redacted] N. 16th St.	Boise	ID	83702
09/12 - 12/13	[redacted] Greenwood Ave N	Seattle	WA	98103
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Norco Inc				From - To (MM/YY – MM/YY): 01/14 - Current
Business Address: 1125 W Amity Rd		City: Boise	State: ID	Zip: 83705
Phone: 208-336-1643	Title: CEO			
Description of Duties: Responsible for managing the company's overall operations				

Business Name: Central Welding Supply				From - To (MM/YY – MM/YY): 09/11 - 12/13
Business Address: 13300 38th Ave NE		City: Marysville	State: WA	Zip: 98271
Phone: 260-651-2307	Title: Human Resources			
Description of Duties: Payroll & Benefits				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicole Kissler

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 11, 2023

Date

Please have this section completed in the presence of a Notary Public.

State of Idaho, ss. County of Ada

I, Nicole Kissler, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7. 11 2023

Date

Subscribed and Sworn to before me this 11th day of July, 2023.

Julie F Thomas

Notary Public Signature

JULIE F THOMAS
Comm. No. 29477
NOTARY PUBLIC
Expires: 07/08/2025
STATE OF IDAHO
(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN2153372	10-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-11-2022

NORCO INC
400 W MAIN ST STE 105
BOISE, ID 837027243

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FN2153372	10-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-11-2022

NORCO INC
400 W MAIN ST STE 105
BOISE, ID 837027243

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☑ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FD1760164
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DGN Pharamacy Inc DBA PersonalRX

Physical Address: 20 Murray Hill Parkway Sutie 210

City: East Rutherford State: NJ Zip: 07073

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): 877-230-6030

Fax: 201-438-5050 Contact Email: Compliance@personalrx.com

Website: www.persoanlrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Joseph Skellie

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23972

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Joseph Skellie	NV Pharmacist Registration #: 23972
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:
Name: NA	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): _____

Corporation/Organization Name: DGN Pharmacy Inc dba PersonalRX

Mailing Address: 20 Murray hill Parkway Suite 210

City: East Rutherford State: NJ Zip: 07073

Telephone: 201-430-7300 Email: Larry@personalrx.com

Contact Person Name: Lawrence Margolis

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

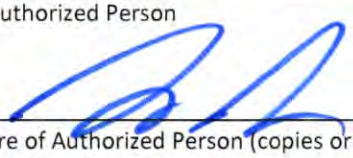
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Founder and Owner (title) for DGN Pharmacy Inc DBA PersonalRX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Lawrence Margolis

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

11/22/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Lawrence Margolis hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Founder and Owner (title) for DGN Pharmacy Inc DBA PersonalRX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 22 day of November, 2023

Notary Public

Cheryl Fine
NOTARY PUBLIC
State of New Jersey
ID # 50107475
My Commission Expires 6/24/2024

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lawrence Margolis

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/22/2023

Date

Board Use Only	Date Received: 12/11/23	Amount: $500 - check #1917341

Personal Rx
Make the right call

November 27, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite
206 Reno, NV 89521

Re: DGN Pharmacy, Inc. d/b/a Personal Rx Notice of Alabama Board of Pharmacy Fine Mail Order Pharmacy
(License # 114490)

To Whom It May Concern:

The Alabama administrative action arose from Pharmacy's purported failure to timely submit a written action plan in replacing Pharmacy's Alabama pharmacist-in-charge ("PIC"). However, notwithstanding the language in the Consent Order, we believed that Personal Rx was, in fact, compliant with Alabama law because the Pharmacy had notified the Alabama Board of Pharmacy that it had a plan to replace the PIC and that the Pharmacy had registered the replacement PIC for the appropriate licensing exam. Since Alabama has published no formal plan requirements or forms, we assumed that the Pharmacy was compliant with applicable requirements in the absence of negative feedback from the Board.

The Pharmacy agreed to pay an administrative fine in the amount of $2,000 to the Alabama Board of Pharmacy, rather than incur significant legal fees to contest the action. A copy of the Consent Order with the Alabama State Board of Pharmacy is also attached.

Accordingly, this matter was the result of a miscommunication with the Board of Pharmacy, rather than Pharmacy's negligent or intentional failure to comply with applicable regulations. Since that time, the Pharmacy has enhanced its procedures when a PIC leaves. The Pharmacy now requires proactive contact with the impacted Board of Pharmacy to confirm compliance with all related Board of Pharmacy requirements and procedures. Moreover, Pharmacy has an outstanding record of licensing compliance throughout its 13 years of operation, and would be pleased to provide any additional information that the Board may request.

Please contact me if you require any additional information.

Very truly yours,

Lawrence Margolis
Founder/CEO

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
DGN PHARMACY, INC. dba PERSONAL RX	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 114490	)	**CASE NO: 21-L-0190**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against DGN Pharmacy, Inc. dba Personal Rx which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the Board through its counsel and DGN Pharmacy, Inc. dba Personal Rx, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds that DGN Pharmacy, Inc. dba Personal Rx has violated the provisions of law based upon the conduct set out in Counts One and Two of the Statement. Count Three shall be dismissed.

2. DGN Pharmacy, Inc. dba Personal Rx shall pay an administrative fine in the amount of Two Thousand Dollars ($2,000.00) within thirty (30) days of the effective date of this Consent Order, that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall DGN Pharmacy, Inc. dba Personal Rx attempt to discharge the same.

3. DGN Pharmacy, Inc. dba Personal Rx expressly waives its rights pursuant

to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §41-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. DGN Pharmacy, Inc. dba Personal Rx further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, DGN Pharmacy, Inc. dba Personal Rx hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. DGN Pharmacy, Inc. dba Personal Rx acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against DGN Pharmacy, Inc. dba Personal Rx's permit, including, but not limited to revocation.

6. That DGN Pharmacy, Inc. dba Personal Rx acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. DGN Pharmacy, Inc. dba Personal Rx acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on

the advice of their attorney.

DONE this the 1st of August, 2022.

DGN PHARMACY, INC. DBA PERSONAL RX

BY: _____

ITS: CEO

_____

John Jones, Attorney for DGN Pharmacy, Inc. dba Personal Rx

DONE this the 9th of August, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: _____

Chris Phung, R.Ph., President

By: _____

James S. Ward,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
DGN PHARMACY, INC. dba PERSONAL RX	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit No.: 114490	)	**CASE NO: 21-L-0190**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: DGN Pharmacy, Inc.
dba Personal Rx
20 Murray Hill Parkway
Suite 210
East Rutherford, New Jersey 07073

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92 (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on August 16, 2022 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate DGN Pharmacy, Inc. dba Personal RX should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that DGN Pharmacy, Inc. dba Personal RX has been guilty of the following, to wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(12) in that you violated Board Rule 680-X-2.12(8) by not being unable to maintain a designated Supervising Pharmacist and failing to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist to-wit: Cynthia Davies Aebli ceased to be your Supervising Pharmacist on or about July 2, 2021; however, as of the date of this

Statement of Charges and Notice of Hearing the Board has not received said action plan.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of the preceding Count.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT THREE

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16th day of December, 2021.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

JOSH GREEN, M.D.
GOVERNOR | KE KIA'ĀINA

SYLVIA LUKE
LIEUTENANT GOVERNOR | KA HOPE KIA'ĀINA

NADINE Y. ANDO
DIRECTOR | KA LUNA HO'OKELE

ESTHER BROWN
COMPLAINTS AND ENFORCEMENT OFFICER

STATE OF HAWAII | KA MOKU'ĀINA 'O HAWAI'I
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
KA 'OIHANA PILI KĀLEPA
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
TELEPHONE: (808) 586-2660
FAX: (808) 586-2670
cca.hawaii.gov/rico

HILO OFFICE
120 PAUAHI STREET, SUITE 212
HILO, HAWAII 96720

KONA OFFICE
HUALALAI CENTER
75-170 HUALALAI ROAD, SUITE C-309
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
BUSINESS: 2145 WELLS STREET, #106
WAILUKU, HAWAII 96793
MAILING: PO BOX 1049
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, SUITE 204
LIHUE, HAWAII 96766

January 6, 2023

Lawrence H. Margolis
DGN Pharmacy Inc., dba Personal Rx
20 Murray Hill Parkway, Suite 210
East Rutherford, New Jersey 07073

RE: RICO Case No. PHA 2022-99-L, PMP-1207

To Mr. Margolis:

I am a staff attorney at the Regulated Industries Complaints Office ("RICO"), Department of Commerce and Consumer Affairs, State of Hawai'i and I have been assigned the above-mentioned case.

RICO has received your letter indicating that DGN Pharmacy Inc., dba Personal Rx ("Personal Rx"), has entered into a Consent Order ("Order") in Case No. 21-L-0190 before the Alabama State Board of Pharmacy ("Alabama Board"). In the Order, the Alabama Board found two violations of Alabama law for failing to maintain a designated Supervising Pharmacist and failing to notify the Alabama Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist.

Under the Hawai'i Revised Statues ("HRS"), the Hawai'i Board of Pharmacy ("Hawai'i Board") may also take disciplinary action against Personal Rx. HRS §§436B-19(13), 461-21(a)(5) provide for disciplinary action where the Hawai'i Board may revoke and/or fine a permit holder for the violation of any state or federal drug, controlled substance, or poison law.

You may also recall, Personal Rx was the subject of a previous RICO investigation and Settlement Agreement, in RICO Case No. PHA 2016-3-L. The prior Settlement Agreement (see enclosures) also allows the Hawai'i Board to pursue additional disciplinary action as the Hawai'i Board deems appropriate for violations of any of the statutes or rules governing the conduct of miscellaneous permit holders (paragraph C.3.).

Enclosed please find a proposed Settlement Agreement which calls for a fine of one thousand dollars ($1,000.00). If the terms of the Settlement Agreement are acceptable, please execute where indicated and return it to me at the address listed above. The administrative fine must be paid by **cashier's check or money order** made payable to **"DCCA - Compliance Resolution Fund"** at the time the Settlement Agreement is returned to RICO. Please note, any Settlement Agreement entered into must be approved by the Hawai'i Board to be effective.

This settlement offer will expire by the close of business on **Friday, February 3, 2023**. If our office does not receive a response by the above deadline, I will assume that Personal Rx does not wish to settle and will proceed accordingly. Thank you for your cooperation in resolving this matter. Please contact me at (808) 586-2660 or *hhopkins@dcca.hawaii.gov* if you have any questions or concerns.

I look forward to hearing from you.

Respectfully,

/s/ Hailialoha Hopkins

HAILIALOHA HOPKINS
RICO Staff Attorney

HDH:jla

Enclosures

HAILIALOHA D. HOPKINS 10707
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawai'i
Leiopapa A Kamehameha Building
235 South Beretania Street, 9th Floor
Honolulu, Hawai'i 96813
Telephone: (808) 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAI'I

In the Matter of the Miscellaneous Permit of DGN PHARMACY INC., dba PERSONAL RX, Respondent.	PHA-2022-99-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS 1-2

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE ("RICO" or "Petitioner"), through its attorney, and Respondent DGN PHARMACY INC dba PERSONAL RX ("Respondent" or "Personal Rx"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was permitted as a miscellaneous permit holder by the Board of Pharmacy, Professional and Vocational Licensing Division, Department of Commerce and Consumer Affairs, State of Hawai'i ("Board"), permit number PMP 1207, issued on or about October 22, 2015 ("permit"). This permit is set to expire or forfeit on or about December 31, 2023.

2. Respondent's mailing address for purposes of this action is 20 Murray Hill Parkway, Suite 210, East Rutherford, New Jersey 07073.

3. On or about December 16, 2021, Personal Rx, was issued a Statement of Charges and Notice of Hearing ("Charges") by the Alabama Board of Pharmacy ("Alabama Board") ("Exhibit A to Exhibit 1") that detailed the following counts:

a. Count One: *Code of Alabama* (1975), § 34-23-33(12) violation of Board Rule 680-X-2.12(8), failing to maintain a designated Supervising Pharmacist and failing to notify the Board within ten (10) days with an action plan to designate another pharmacist as Supervising Pharmacist.

b. Count Two: *Code of Alabama* (1975), § 34-23-33(13) violation of Board Rule 680-X-2.22(2)(d), the duty to observe the law, to uphold the dignity and honor of the profession, and to accept its ethical principles. A pharmacist and a pharmacy should not engage in any activity that will bring discredit to the profession and should expose, without fear or favor, illegal or unethical conduct in the profession.

c. Count Three: *Code of Alabama* (1975), § 20-2-54(a)(4) by violating the provisions of *Code of Alabama* (1975), § 34-23-1 *et. seq.*, said violation being based upon the allegations contained in any or all of the preceding counts.

4. On or about August 1, 2022, Personal Rx entered into a Consent Order ("Order") before the Alabama State Board of Pharmacy ("Alabama Board") ("Exhibit 1").

5. The Order was adopted by the Alabama Board on August 9, 2022. Its terms included finding a violation of counts one and two of the Charges and an administrative fine of two thousand dollars ($2,000.00).

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawai'i Revised Statutes ("HRS") §436B-19(13) (disciplinary action by another state or federal agency); HRS §436B-19(15) (failure to report discipline in writing within thirty days); and HRS §461-21(a)(5) (disciplinary action for the violation of any state or federal drug, controlled substance, or poison law).

7. RICO alleges Respondent was previously disciplined by the Board in RICO Case No. PHA 2016-3-L relating to disciplinary action taken by the State of New Jersey for the alleged acceptance of an unsigned prescription. A copy of the filed Settlement Agreement is attached hereto as ("Exhibit 2")

8. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. RESPRESENTATIONS BY RESPONDENT

1. Respondent enters into this Settlement Agreement freely, knowingly, intelligently, voluntarily, and under no coercion or duress.

2. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, intelligently, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

3. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension, or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

4. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents Exhibit A to Exhibit 1 is a true and correct copy of the Charges by the Alabama Board

6. Respondent represents Exhibit 1 is a true and correct copy of the Order by the Alabama Board.

7. Respondent represents Exhibit 2 is a true and correct copy of the previous Settlement Agreement in RICO Case No. PHA 2016-3-L before the Hawai'i Board.

8. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

9. Respondent acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

10. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

11. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2022-99-L.

12. Respondent acknowledges that upon its approval, this Settlement Agreement constitutes disciplinary action and understands that this Settlement Agreement may be subject to reporting requirements.

13. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

[continued on next page]

C. TERMS OF SETTLEMENT

1. Administrative Fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, ATTN: Hailialoha D. Hopkins, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Revocation. In the event that Respondent fails to abide by any of the terms of this Settlement Agreement, Respondent agrees to the revocation of its permit without further hearing by the Board upon the filing of an affidavit by RICO attesting to any such failure by Respondent. If Respondent's permit is revoked, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice that its permit has been revoked. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawai'i, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., C.7., C.8., and C.9. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board. Respondent understands and agrees that RICO and the staff of the Board may communicate directly with the Board regarding this Settlement Agreement, without notice to or participation by Respondent or its counsel. By signing this Settlement Agreement, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the Settlement Agreement prior to the time the Board considers and acts upon it.

5. Electronic and Facsimile Copies. The parties understand and agree that electronic and facsimile copies of this Settlement Agreement, including electronic and facsimile signatures thereto, shall have the same force and effect as wet-ink originals.

6. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against

Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

7. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

8. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent, or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

9. Complete Agreement. This Settlement Agreement is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Settlement Agreement may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that s/he is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: East Rutherford (City) NJ (State), _____ (Date).

DGN PHARMACY INC., dba PERSONAL RX
Respondent

By: _____ (Signature)

Lawrence Margolis (Print Name)

Its Founder and CEO (Print Title)

DATED: Honolulu, Hawai'i, _____.

HAILIALOHA D. HOPKINS
Attorney for Department of Commerce
and Consumer Affairs

APPROVED AS TO FORM:

JOHN JONES
Attorney for Respondent

DIGINO'S APOTHECARY
255 Valley Boulevard
Wood-Ridge, New Jersey 07075
Phone (201) 430-7300 | Fax (201) 334-0700

James E. Hennig, R.Ph.
Pharmacist-in-Charge
jim@grouprx.net

Via Federal Express

Attention: Pharmacy Board of Pharmacy

Re: **Applicant: Digino's Apothecary**
Explanation and Documentation of Disciplinary Action Taken Against Applicant's Pharmacy License

Dear Board of Pharmacy Members:

This letter has been submitted with the application of Digino's Apothecary for a Mail Service Pharmacy Permit. In accordance with the application, this letter explains all disciplinary action taken against the applicant's pharmacy license, and documentation of such action is attached hereto. No disciplinary action whatsoever has been taken against any license of the pharmacist-in-charge, and therefore this letter applies only to the applicant-pharmacy.

The New Jersey Board of Pharmacy disciplined Digino's Apothecary twice. The first time was in July 2012 for a violation of the requirement that the pharmacy's label include "use by" information. The required information was omitted from the label due to a computer programming issue that resulted in the information being printed on labels for new prescriptions but not printed on labels for refilled prescriptions. This computer glitch was corrected as soon as the pharmacy became aware of it. The July 2012 discipline also referenced a single misbranded medication, a pharmacist without a name tag, and the failure to display the PIC's license. Digino's Apothecary took prompt action to correct these issues. (Documentation of the July 2012 disciplinary action is attached hereto as **Exhibit 1**.)

The New Jersey Board of Pharmacy disciplined Digino's Apothecary a second and last time in July 2015. That discipline—a $25 fine—resulted from the filling of a prescription for ADHD medication that had not been signed by the prescriber. The prescription was for a patient for whom the physician had, for more than three years, routinely prescribed the medication for daily use. The failure to ensure that the prescription was signed was an oversight. In the wake of this incident, Digino's Apothecary has reinforced its policies and procedures for accepting, filling and checking prescriptions to ensure that this kind of error is not repeated. The July 2015 discipline also included a warning for the use of labels for generic drugs that do not print the phrase "generic for" before the name of the brand-name drug. Digino's Apothecary promptly modified its pharmacy's computer software to ensure compliance with New Jersey's

prescription-labeling requirement. (Documentation of the July 2015 disciplinary action is attached hereto as Exhibit 2.)

The Hawaii Board of Pharmacy took reciprocal disciplinary action against Digino's Apothecary with respect to the July 2015 New Jersey disciplinary action, because the New Jersey discipline was not timely reported to Hawaii. Digino's Apothecary was not licensed in Hawaii at the time of the New Jersey discipline. Digino's Apothecary began filling out and substantially completed its Hawaii license application before the July 2015 discipline, but it did not submit the application until September 2015. Prior to doing do, it did not update the application to include the July 2015 discipline, and its submitted application disclosed only the July 2012 New Jersey disciplinary action. (Documentation of the Hawaii reciprocal disciplinary action is attached hereto as Exhibit 3.)

Please do not hesitate to contact me by phone or e-mail if you require additional information regarding the disciplinary actions referenced in this letter.

Sincerely

James E. Hennig, R.Ph.
Pharmacist-In-Charge

JEH/tpb
Attachments

91478

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark, NJ 07102

JEFFREY S. CHIESA
Attorney General

ERIC T. KANEFSKY
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 17, 2012

Dimitriy Notkin, RPIC
Digino's Apothecary
255 Valley Boulevard
Wood Ridge, New Jersey 07075

Re: Inspection Report #8-5973-12-X
Date of Inspection: March 16, 2012

Dear Dimitriy Notkin:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you MUST SIGN THE ATTACHED CERTIFICATION and agree to the following:

1. PAY A PENALTY IN THE AMOUNT OF $375.00 and PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Ruhmannio, R.Ph.
Executive Director

AR:rh
(6/2012)

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

ATTACHMENT A

9. Digino's Apothecary - 255 Valley Blvd., Wood Ridge, New Jersey 07075
   Pharmacist-In-Charge: Dimitriy Notkin
   Bureau File #8-5973-12-X, Period: 3/16/12
   Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-7.18 N.J.A.C.13:39-6.2(f)7	One (1) misbranded medication was found in the active drug stock inventory.	$25.00
N.J.A.C.13:39-2.10(b)	RPIC current renewal certificate was not displayed.	$50.00
N.J.A.C.13:39-6.3	No name tag worn by pharmacist.	$50.00
N.J.A.C.13:39-7.12(a)(b)13l	Prescription label "Use By" deficiency.	$250.00
TOTAL: $375.00		

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
24 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

CERTIFICATION

I, LAWRENCE MARGOLIS, hereby acknowledge that I have read and reviewed the Board's letter dated July 17, 2012 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

☐ I acknowledge the conduct which has been charged and agree to:

1. Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of $375.00 (to be paid upon signing of this certification).
2. Send a Letter of Corrective Action, as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

☒ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

(Signature)

Dated: 9/26/2012

Lawrence H. Margolis
(Print Name)

Ref: Dimitriy Notkin, RPIC
Digino's Apothecary
255 Valley Boulevard
Wood Ridge, New Jersey 07075
(28RS00644100)
Inspection Report #8-5973-12-X
AR/rh
(6/2012)

STATE OF NEW JERSEY
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

WILENTZ
WILENTZ, GOLDMAN & SPITZER P.A.
ATTORNEYS AT LAW
90 Woodbridge Center Drive
Suite 900 Box 10
Woodbridge, NJ 07095-0958
732.636.8000
Fax 732.855.6117

Meridian Center I
Two Industrial Way West
Eatontown, NJ 07724-2264
732.542.4500
Fax 732.493.8387

110 William Street
26th Floor
New York, NY 10038-3927
212.267.3091
Fax 212.267.3828

Two Penn Center Plaza
Suite 910
Philadelphia, PA 19102
215.940.4000
Fax 215.636.3999

www.wilentz.com

Please reply to:
Woodbridge

DAVID T. WILENTZ (1918-1996)
G. GEORGE GOLDMAN (1922-1996)
HENRY M. SPITZER (1925-1984)
WARREN W. WILENTZ (1949-2010)

FREDERIC K. BECKER
RICHARD P. LERT
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PETER A. GREENBAUM
WILLARD C. EIGI
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RICHARD J. BYRNES
JAMES E. TORREY, JR.
DEFORE WOLFF PACHECO
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ABBY FREEMAN-FARGHAN
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GLENN P. PRIVES
ANNEMARIE T. GREENAN
KATHERINE A. CZECH

Certified Civil Trial Attorney
Certified Criminal Trial Attorney
Certified Workers Comp. Attorney
1 Not admitted NJ
2 Admitted NY
3 Admitted PA
4 Admitted CT
5 Admitted DC
6 Admitted MA
7 Admitted MD
8 Admitted VA
9 Admitted CA
10 Admitted FL
11 Admitted PR
12 Admitted VI

Certified Article Number
7196 9008 9111 5125 1657
SENDERS RECORD

August 9, 2012

VIA REGULAR & CERTIFIED MAIL:R.R.R.
New Jersey Board of Pharmacy
124 Halsey Street, 6th Floor
P.O. Box 45013
Newark, New Jersey 07101
Attn: Anthony Rubinaccio, Executive Director

Re: Digino's Apothecary
Inspection Report No. 8-5973-12-X

Dear Director Rubinaccio:

Please be advised that I am in receipt of your letter dated July 17, 2012, enclosed herewith for your reference. That letter discusses the recent inspection of Digino's Apothecary, conducted on March 16, 2012 and the subsequent report issued by the inspector. We respectfully contest an issue identified therein. Accordingly, for the reasons set forth below, we request that the Board mitigate its findings.

The primary violation related to the pharmacy's label and the "use by" requirement. The pharmacy is aware that its label must include the "use by" date, pursuant to N.J.A.C. 13:39-7.12. In fact all of the pharmacy's new prescriptions included that component. It appears that some refill prescriptions did not, due to a error with the computer system. As demonstrated by way of the attached images, that technical glitch has been resolved.

In light of this information, and the corrective action taken by Digino's Apothecary, we do not believe any further action is required by the Board as to this issue. Therefore, we respectfully request the Board

WILENTZ, GOLDMAN & SPITZER P.A.

mitigate the Uniform Penalty Letter to reflect a reduction on the fine related to this violation.

Please feel free to contact me if there are any questions regarding the above.

Very truly yours,

ANGELO J. CIFALDI

AJC/cg
Enclosures
cc: Lawrence Margolis

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 5-14-15
File number:

Board of Pharmacy Inspection Report

DIGINO'S APOTHECARY
Pharmacy trade name

Corporation name (if not the same)

Owner (as listed with the corporation or limited liability company)

255 VALLEY BLVD.
Street address

WOOD RIDGE NJ 07075
City State Zip code

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

DIGINO'S PHARMACY | 28RS00697100 | 6/30/15
Name of permit holder | Certificate number | Expiration date

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

D0594400 | 10/31/14
Certificate number | Expiration date

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

FD1760164 | 6/30/15
Certificate number | Expiration date

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): JAMES E. HENNIG
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

28RI01673200 | 4/30/15 | 40+
Permit number | Expiration date | Hours worked per week

1. Is the registered pharmacist-in-charge's current renewal on display? ☒ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
(Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.)

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☒ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
JAMES E. HENNIG R.P.	R.P.I.C.	28RI01673200	☒ Yes ☐ No	40+
JONATHAN WILLIAMS	PHARMACY TECHNICIAN	28RW00356100	☒ Yes ☐ No	40
ROBERTO MIRASOL	PHARMACY TECHNICIAN	28RW01907200	☒ Yes ☐ No	40
BRIAN C LUKEMAN	PHARMACY TECHNICIAN	28RW01787600	☒ Yes ☐ No	40
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.6(a)8 and 13:39-5.6]

Date:	8-14-2014
Time entered:	10:00AM
Time departed:	10:25 AM

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: DIGILO'S APOTHECARY

Address: 255 VALLEY BLVD., WOOD-RIDGE, NJ 07075

Name and registration number of pharmacist-in-charge:
JAMES E. HENNIG, RPIC 28RI01693200
(If pharmacist-in-charge not present, give name and # of R.P. on duty)

The following deficiencies have been noted:

[13:45H-7.5(A)] [13:45H-7.8(A)] - THE PHARMACY ACCEPTED AND FILLED A PRESCRIPTION FOR A C-II CDS MEDICATION THAT HAD NOT BEEN MANUALLY SIGNED BY THE PRESCRIBER. SPECIFICALLY, R. N016380 FILLED ON 7/28/14 WITH THIRTY DEXMETHYLPHENIDATE SAE TABLETS HAD NOT BEEN SIGNED BY THE PRESCRIBER.

[13:39-7.12(A)] - ON THE PRESCRIPTION LABELS IN USE, THE PHARMACY COMPUTER IS NOT PRINTING THE PHRASE "GENERIC FOR:" FOLLOWED BY THE NAME OF THE POPULAR BRAND NAME DRUG PRESCRIBED (SEE SURVEYS #1-#5 OF THE ATTACHED PRESCRIPTION DISPENSING ANALYSIS SURVEY).

108310

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark, NJ 07102

JOHN J. HOFFMAN
Acting Attorney General

STEVE C. LEE
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 27, 2015

James E. Hennig, RPIC
Digino's Apothecary
255 Valley Blvd.
Wood Ridge, New Jersey 07075

Re: Inspection Report #5973-14-X
Date of Inspection: August 14, 2014

Dear James E. Hennig:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on **Attachment A.**

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

> **PAY A PENALTY IN THE AMOUNT OF $25.00** and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST, 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

11/23/99

its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, R.Ph.
Executive Director

AR/mb
(03/15)

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45045
NEWARK, NJ 07101

CERTIFICATION

I, James Hennig, hereby acknowledge that I have read and reviewed the Board's letter dated July 27, 2015 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

☑ I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of $25.00** (to be paid upon signing of this certification).
2. **Send a Letter of Corrective Action,** as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

☐ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

(Signature)

Dated: 8/4/15

James Hennig
(Print Name)

Ref: James E. Hennig, RPIC
Digino's Apothecary
255 Valley Blvd.
Wood Ridge, New Jersey 07075
(28RS00699100)
Inspection Report #8-5973-14-X

AR/mb
(03/15)

AUG 5

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

ATTACHMENT A

50. Digino's Apothecary - 255 Valley Blvd., Wood Ridge, New Jersey 07075
Pharmacist-In-Charge: James E. Hennig
Bureau File #8-5973-14-X, Period: 08/14/2014
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18 and N.J.S.A.45:14-48(a)11&12.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:45H-7.5(a) N.J.A.C.13:45H-7.8(a)	The pharmacist accepted and filled a prescription for a C-II CDS medication that had not been signed by the prescriber. In particular, Rx #N0163860, filled on 07/28/2014, had not been signed by the prescriber.	$25.00
N.J.A.C.13:39-7.12(a)	On the prescription labels in use, the pharmacy computer is not printing the phrase "Generic For:" followed by the name of the popular brand name drug prescribed.	Warning
TOTAL: $25.00		

DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY ST., 6TH FL., P.O. BOX 45013
NEWARK, NJ 07101

WILENTZ
WILENTZ, GOLDMAN & SPITZER P.A.

ATTORNEYS AT LAW
90 Woodbridge Center Drive
Suite 900 Box 10
Woodbridge, NJ 07095-0958
732.636.8000
Fax 732.855.6117

Meridian Center I
Two Industrial Way West
Eatontown, NJ 07724-2265
732.542.4800
Fax 732.493.8387

110 William Street
20th Floor
New York, NY 10038-3827
212.267.3091
Fax 212.267.3825

Two Penn Center Plaza
Suite 910
Philadelphia, PA 19102
215.940.3000
Fax 215.830.3899

www.wilentz.com

Please reply to:
Woodbridge
Direct Dial: (732) 855-6088
Direct Fax: (732) 726-6814

August 6, 2015

VIA REGULAR MAIL & E-MAIL (anthony.rubinaccio@lps.state.nj.us)
New Jersey Board of Pharmacy
124 Halsey Street, 6th Floor
Newark, New Jersey 07101
Attn: Anthony Rubinaccio, Executive Director

Re: Digino's Apothecary
Uniform Penalty Letter

Dear Director Rubinaccio:

Please be advised that I represent the above-referenced pharmacy. We are in receipt of your letter, dated February 22, 2013. Enclosed please find a check, payable to the Board, in the amount of $25.00 and a fully executed copy of the Board's certification. The pharmacy has taken corrective action measures to address the issue underlying this Uniform Penalty Letter.

Should you have any questions on the above, please do not hesitate to contact me.

Very truly yours,

ANGELO J. GIFALDI

AJC/cg
Enclosures
cc: Mr. James Hennig

#8148544.1(157793.002)

DAVID Y. IGE
GOVERNOR

SHAN S. TSUTSUI
LIEUTENANT GOVERNOR

CATHERINE P. AWAKUNI COLÓN
DIRECTOR

CELIA C. SUZUKI
LICENSING ADMINISTRATOR

STATE OF HAWAII
PROFESSIONAL AND VOCATIONAL LICENSING DIVISION
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
P.O. BOX 3469
HONOLULU, HAWAII 96801
http://cca.hawaii.gov/pvl

April 4, 2016

DGN Pharmacy, Inc., dba Digino's Apothecary
c/o James E. Hennig
255 Valley Boulevard
Wood-Ridge, New Jersey 07075

Daria A. Loy-Goto, Staff Attorney
John T. Hassler, Staff Attorney
Regulated Industries Complaints Office
Department of Commerce & Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813

Re: In the Matter of the Miscellaneous Permit of DGN Pharmacy, Inc., doing business as Digino's Apothecary; PHA 2016-3-L

Dear Mr. Hennig, Ms. Loy-Goto and Mr. Hassler:

The Board of Pharmacy, at its meeting on March 31, 2016, approved the above-referenced Settlement Agreement.

Very truly yours,

LEI S. FUKUMURA
Special Deputy Attorney General

LSF:jaf

DARIA A. LOY-GOTO 6175
JOHN T. HASSLER 5311
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorneys for Department of Commerce
and Consumer Affairs

2016 FEB 11 A 9:59

DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2016 APR -1 P 2:
HEARINGS OFFIC

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of)	PHA 2016-3-L
)	
DGN PHARMACY, INC., DOING)	SETTLEMENT AGREEMENT PRIOR TO
BUSINESS AS DIGINO'S)	FILING OF PETITION FOR DISCIPLINARY
APOTHECARY,)	ACTION AND BOARD'S FINAL ORDER;
)	EXHIBIT "1"
Respondent.)	
)	

24104221

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent DGN PHARMACY, INC., doing business as DIGINO'S APOTHECARY (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under permit number PMP 1207. The permit was issued on or about October 22, 2015. The permit will expire or forfeit on or about December 31, 2017.

2. Respondent's mailing address for purposes of this action is 255 Valley Boulevard, Wood-Ridge, New Jersey 07075.

3. RICO received a request for investigation from the Board after Respondent reported disciplinary action by the State of New Jersey on a December 9, 2015 renewal application.

4. Respondent attached a copy of a Certification from the New Jersey Board of Pharmacy issued to Respondent following Inspection Report #5973-14-X (hereinafter "the New Jersey Certification") (Exhibit "1"). The New Jersey Certification was based on alleged acceptance of an unsigned prescription. Respondent was issued a warning and a $25.00 fine was imposed.

5. RICO alleges that disciplinary action was taken against Respondent by the State of New Jersey and that Respondent failed to timely report that action.

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 436B-19(15) (failure to timely report disciplinary action).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a miscellaneous permit holder by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent represents Exhibit "1" is a true and correct copy of the Certification from the New Jersey Board of Pharmacy issued to Respondent following Inspection Report #5973-14-X.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this settlement agreement may be grounds for further disciplinary action under HRS chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2016-3-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of TWO HUNDRED AND NO/100 DOLLARS ($200.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: John T. Hassler, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

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DATED: Hackensack (CITY), New Jersey (STATE), 2/5/16.

DGN PHARMACY, INC., DOING BUSINESS AS DIGINO'S APOTHECARY
Respondent

By: _____
Its Director of Pharmacy

DATED: Honolulu, Hawaii, February 11, 2016.

_____
DARIA A. LOY-GOTO
JOHN T. HASSLER
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF DGN PHARMACY, INC., DOING BUSINESS AS DIGINO'S APOTHECARY; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; CASE NO(S). PHA 2016-3-L

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF DGN PHARMACY, INC., DOING BUSINESS AS DIGINO'S APOTHECARY; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; CASE NO(S). PHA 2016-3-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

Kerri Okamura
KERRI OKAMURA
Chairperson

3/31/16
DATE

GARRETT A. LAU
Vice Chairperson

MARCELLA CHOCK

MARY JO KEEFE

Carolyn Ma
CAROLYN S. J. MA

PVL 07/01/15

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF DGN PHARMACY, INC., DOING BUSINESS AS DIGINO'S APOTHECARY; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"; CASE NO(S). PHA 2016-3-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

KERRI OKAMURA
Chairperson

3/31/16
DATE

GARRETT A. LAU
Vice Chairperson

Marcella Sho Chock
MARCELLA CHOCK

Mary Jo Keefe
MARY JO KEEFE

CAROLYN S. J. MA

PVL 07/01/15

STATE OF New Jersey)
) SS.
COUNTY OF Bergen)

On this 8th day of Feb, 2016, before me personally appeared James Hennig, RPh, to me known to be the person described, and who executed the foregoing instrument on behalf of Digino's Apothecary as its Pharmacist-in-Charge, and acknowledged that he/she executed the same as his/her free act and deed.

This 5TH-page OF 7 PAGES document dated FEBRUARY 8, 2016 was acknowledged before me by JAMES E. HENNIG this 8TH day of FEBRUARY, 2016, in the City of EAST RUTHERFORD, in the County of BERGEN, in the State of ~~Hawaii~~. New Jersey

EDGAR DUBON
Notary Public
State of New Jersey
My Commission Expires Aug 6, 2019

Name:
Notary Public, State of ~~Hawaii~~ New Jersey

My Commission expires: 08/06/2019

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

DGN PHARMACY INC
0400282331

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on April 17, 2009.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

LAWRENCE MARGOLIS
20 MURRY HILL PARKWAY
SUITE 210
EAST RUTHERFORD, NJ 07073

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 20th day of October, 2023

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6147599418

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 11/17/2022
File number: 8-5973-22-1864

Board of Pharmacy Inspection Report

Personal Rx
Pharmacy trade name

Corporation name (if not the same)

Owner (as identified on the occasion of this inspection)

20 Murray Hill Parkway Suite 210
Street address

City State ZIP code
East Rutherford, NJ 07073

PERSONALRX
20 MURRAY HILL PKWY #210
EAST RUTHERFORD, NJ
07073-2164
Phone: 877-230-6030

RX# 0325818 00 Rph: JZ D/F 11/16/2022 D/W 11/15/2022
ABERCROMBIE, KATHRYN
100 E MILES RD LOT 6
CARROLLTON, GA 30116-9263
TAKE 2 TABLETS BY MOUTH ONCE DAILY AT BEDTIME AT 10PM

TRAZODONE 300 MG TABLET
Generic for Desyrel Qty 60
DR. JOHANNES Mfg:Apo
(03) REFILLS REMAINING UNTIL 11/15/2023 Use By 11/16/2023

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Personal Rx (Name of permit holder) 28RS00699100 (Certificate number) 6·30·2023 (Expiration date)

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

D09594400 (Certificate number) 10·31·2024 (Expiration date)

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

FD1760164 (Certificate number) 1·31·2025 (Expiration date)

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Joseph F. Ziobro
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☒ Yes ☐ No)

28RI04025800 (Permit number) 4·30·2023 (Expiration date) 40 (Hours worked per week)

1. Is the registered pharmacist-in-charge's current renewal on display? ☒ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☒ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
			☐ Yes ☐ No	
			☐ Yes ☐ No	
SEE ATTACHED			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☒ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☒ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R.-1700.14/15] Is a representative inventory of safety closures present? ☒ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☒ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☒ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☐ Yes ☒ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☒ Yes ☐ No
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☒ Yes ☐ No

[signature] Print the name of the registered pharmacist who was present for the survey

Joseph Ziobro
Signature of the registered pharmacist who was present for the survey

Kapetanakis
Signature of the Enforcement Bureau Representative

1 of 4

Form EB-02 (10/12)

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: Personal Rx Date: 11/17/22
Street Address: 20 Murray Hill Parkway Suite 210
City, State, ZIP: East Rutherford, NJ 07073
Kapetanakis
Inspector

Initials of Registered Pharmacist	Quantity or Commercial Package Size	The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.				Deficiencies [13:39-7.18] [13:39-6.2(f)7]						
		Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.		Random Shelves -										
7.		Selected										
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

NO deficiencies found

COMMENTS:

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

Joseph Ziobro
PRINTED NAME OF PHARMACIST

SIGNATURE OF PHARMACIST

EB-23A (1/05)

Date: 11/1/2022
Time entered: 10:45am
Time departed: 2:30pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: Personal Rx
Address: 20 Murray Hill Parkway Suite 210 East Rutherford 07073
Name and registration number of pharmacist-in-charge:
Joseph Zlobro (Harned) PIC 28RI04025800
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted: Routine Inspection

13:39-10.3(a)(b)1 The Subject pharmacy failed to Submit to the Board a self-inspection of the automated medication system documented on a form provided by the Board prior to use for the first time and failed to conduct an annual self-inspection of the automated system documented on a form provided by the Board.

13:39-6.1(b) The current biennial renewal registration issued by the Board is not conspicuously displayed
• Ja'Miya Casta 28RI04514700

13:39-5.8(a) The Subject pharmacies library lacked a current reference text for the General practice of pharmacy required reference text.
• Pharmacotherapy A pathophysiologic Approach 2nd Edition.

13:39-10.4(a)1-8(c) The Subject pharmacy failed to provide a copy of the written policies and procedures of operation adopted pursuant to this Section and shall be retained @ the pharmacy.

~~13:39-5.11(a)ii, iii, iv~~ DK

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

(Signature of the Pharmacist identified above)

EB-33 3/07

Date: 11/17/27
Time entered: 10:45 am
Time departed: 2:30 pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: Personal Rx
Address: 20 Murray Hill Parkway Suite 210 East Rutherford 07073
Name and registration number of pharmacist-in-charge:
Joseph Zlobiro (Hamedl) PIC 28RI-04025800
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty)

The following deficiencies have been noted: Routine Inspection

13:39-5.11 (d) iii, iii The Subject pharmacies temperature policy and procedure failed to include the following
- maintain temperature logs for two (2) years
- in the Event of an excursion lasting greater than 24 hours must notify the Board within 48 hours OR
- Excursion lasting ~~more than~~ 72 hours or more pharmacist shall not dispense medication
- Training of all personnel who handle or are responsible for prescription drugs.

Upon further review of documents obtained by this Investigator Further deficiencies may be noted subsequent to the inspection activity

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

(Signature of the Pharmacist identified above)

EB-33 3/07

Personal Rx
Make the right call

List Of All Stockholders 10% or More

Name: Lawrence Margolis
Title: Officer, Director (Founder and CEO)
Percentage: 38%
Address: 20 Murray Hill Parkway suite 210
East Rutherford NJ 07073
Email: Larry@PersonalRX.com
Phone: [redacted]

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER, WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

PERSONAL RX
JOSEPH MERRILL SKELLIE
20 Murray Hill Pkwy., Ste. 210
East Rutherford NJ 07073

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

06/19/2023 TO 06/30/2024
VALID

Signature of Licensee/Registrant/Certificate Holder

28RS00699100
LICENSE/REGISTRATION/CERTIFICATION #

Cari Bais
ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
PERSONAL RX
Pharmacy

06/19/2023 TO 06/30/2024
VALID

SIGNATURE Cari Bais

28RS00699100
License/Registration/Certificate # ACTING DIRECTOR

PLEASE DETACH HERE

IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site PersonalRX

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) NJ: 28RS00699100

Physical Address 20 Murray Hill Parkway Sutie 210

City East Rutherford State NJ Zip 07073

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 877·230·6030 Website www.PersonalRX.com

Licensing Company Email _____

Section 2: Personal Information

First Lawrence Middle _____ Last Margolis

Alias(es, nicknames, name changes, etc.) Larry

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 20 Murray Hill Parkway Sutie 210

City East Rutherford State NJ Zip 07073

Telephone [redacted] Email larry@personalrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/13 - to Present	[redacted] Orchard Drive	Purchase	NY	10577
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7- Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
DGN Pharmacy Inc DBA PersonalRX	April 2014- Present

Business Address	City	State	Zip
20 Murray Hill Parkway suite 210	East Rutherford	NJ	07073

Phone	Title
201-430-7300	Founder and CEO

Description of Duties: Owner of Pharmacy

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties:

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lawrence Margolis
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/22/2023
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Bergen

I, Cheryl Fine, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/22/23
Date

Subscribed and Sworn to before me this 22 day of November, 2023.

Notary Public Signature

Cheryl Fine
NOTARY PUBLIC
State of New Jersey
ID # 50107475
My Commission Expires 6/24/2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: PersonalRX

Pharmacy/Wholesaler License # (if applicable): NJ: 28RS00699100

Physical Address: 20 Murray Hill Parkway Sutie 210

City: East Rutherford State: NJ Zip: 07073

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 877-230-6030 Website: www.personalrx.com

Licensing Company Email:

Section 2: Personal Information

First: Joseph Middle: Last: Skellie

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 20 Muray Hill Parkway Sutie 210

City: East Rutherford State: NJ Zip: 07073

Telephone: [redacted] Email: Jskellie@personalrx.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northeastern University		09/2003 to 05/2009	
Address	**City**	**State**	**Zip**
360 Hungting Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Oneonta High School			
Address	**City**	**State**	**Zip**
130 East St	Oneonta	NY	13820
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/17 to Present	[redacted]Highland Ave	River Vale	NJ	07675
01/16 to 6/17	[redacted]Repton Place	Watertown	MA	02472
12/13 to 12/16	[redacted]West School St	Charlestown	MA	02129
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Personal Rx			From - To (MM/YY – MM/YY): 05/23 to Present	
Business Address: 20 Murray Hill Parkway Suite 210		City: East Rutherford	State: NJ	Zip: 07073
Phone: 201 430 7300	Title: Director of Pharmacy		Number of Employed Hours: 1160	
Description of Duties:				

Business Name: Millers of Wyckoff			From - To (MM/YY – MM/YY): 09/19 to 5/23	
Business Address: 678 Wyckoff Ave		City: Wyckoff	State: NJ	Zip: 07481
Phone: 201 891 3333	Title: COO		Number of Employed Hours: 6240	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Skellie

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/28/2023

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Bergen

I, Joseph Skellie, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/28/2023

Date

Subscribed and Sworn to before me this 28 day of November 2023

Notary Public Signature

Cheryl Fine
NOTARY PUBLIC
State of New Jersey
ID # 50107475
My Commission Expires 6/24/2024

(Seal)

I, Joseph Skellie, **certify that as the designated representative for**

DGN Pharmacy Inc DBA PersonalRX,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JS I am at least 21 years of age;
3. JS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Joseph Skellie
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/28/2023
Date

1:2
347/525
PERSONAL RX
20 MURRAY HILL PKWY STE 210
EAST RUTHERFORD, NJ 07073-2164

10003861 2/000364-1/1-0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD1760164	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-24-2022

PERSONAL RX
20 MURRAY HILL PKWY STE 210
EAST RUTHERFORD, NJ 07073-2164

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD1760164	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-24-2022

PERSONAL RX
20 MURRAY HILL PKWY STE 210
EAST RUTHERFORD, NJ 07073-2164

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-State	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☒ Mail-Order Service
		☒ Other: Mail Order	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Quality Drug Corporation

Physical Address: 18 Technology Drive, Suite 104

City: Irvine State: CA Zip: 92618

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 833-210-5968 Toll Free # (NAC 639.708, NRS 639.23286): 833-210-5968

Fax: 833-210-1416 Contact Email: licensing@lumicera.com

Website: www.lumicera.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Laurel Hipszer

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23971

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy. (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Laurel Hipszer	NV Pharmacist Registration #: 23971
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.) N/A

Name: Brent Eberle	Credentials: WI Pharmacist 12971-40	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Navitus Health Solutions, LLC

Corporation/Organization Name: Lumicera Health Services, LLC

Mailing Address: 361 Integrity Drive

City: Madison State: WI Zip: 53717

Telephone: 855-847-3553 Email: licensing@lumicera.com

Contact Person Name: Alecia Rauch

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Pharmacy Officer (title) for Quality Drug Corporation (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Brent Eberle

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

11/27/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Brent Eberle hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Pharmacy Officer (title) for Quality Drug Corporation (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28 day of November, 2023

Notary Public

JANET L KINDSCHI
Notary Public
State of Wisconsin

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Eberle

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/27/2023

Date

Board Use Only	Date Received: 11/30/23	Amount: $500 - check 66667 6201

Lumicera
Health Services

Owner

Lumicera Health Services, LLC
310 Integrity Drive
Madison, WI 53717
100% owned

Principle Directors

Name: David Wilson Fields
310 Integrity Drive
Madison, WI 53717
Position: President/CEO
% of Ownership: 0%

Name: George Henry Hepburn
310 Integrity Drive
Madison, WI 53717
Position: Chief Financial Officer
% of Ownership: 0%

Name: Brent Joseph Eberle
310 Integrity Drive
Madison, WI 53717
Position: Chief Pharmacy Officer
% of Ownership: 0%

Principal Officers

Name: David Wilson Fields
310 Integrity Drive
Madison, WI 53717
Position: President/CEO
% of Ownership: 0%

Name: George Henry Hepburn
310 Integrity Drive
Madison, WI 53717
Position: Chief Financial Officer
% of Ownership: 0%

Name: Paul Morris Page
310 Integrity Drive

310 Integrity Drive
Madison, WI 53717
P / 855.847.3553
F / 855.847.3558

Lumicera
Health Services

Madison, WI 53717
Position: Secretary/Chief Legal Officer
% of Ownership: 0%

Name: Brent Joseph Eberle
310 Integrity Drive
Madison, WI 53717
Position: Chief Pharmacy Officer
% of Ownership: 0%

310 Integrity Drive
Madison, WI 53717
P / 855.847.3553
F / 855.847.3558

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	1714080		**Inspection Information**
Legal Business Name:	Quality Drug Corporation	**Conference Call Date:**	N/A
Doing Business As (DBA):	Quality Drug Clinical Care	**Start Time: 24-hour format (13:00)**	N/A
Address:	18 Technology Dr, Ste 104	**End Time: 24-hour format (13:00)**	N/A
City:	Irvine	**Onsite Inspection Date:**	4/20/2023
State:	CA	**Start Time: 24-hour format (13:00)**	12:10
Zip Code:	92618	**End Time: 24-hour format (13:00)**	15:50
Telephone number:	949/471-0223	**Inspector Name:**	Nancy Hall, PharmD
Toll free number:	855/847-3553(pt)/855/847-3554(provider)	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	949/404-3760	**Observer Name/Affiliation (if applicable):**	
Website:	www.lumicera.com	**Observer Name/Affiliation (if applicable):**	

Pharmacy Hours of Operation	**Check if 24/7** ☐		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			X
Monday	9:00	18:00	
Tuesday	9:00	18:00	
Wednesday	9:00	18:00	
Thursday	9:00	18:00	
Friday	9:00	18:00	
Saturday			X

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Sebastian Zapart	sebastian.zapart@lumicera.com	236225
Nonsterile Compounding Supervisor	N/A		
Sterile Compounding Supervisor	N/A		
Hazardous Compounding Supervisor	N/A		

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Sebastian Zapart	Pharmacist in Charge	Y
2	Steven Harshe	Pharmacist	Y
3	Christian Cortez	Pharmacy Technician	Y
4	Christopher Brodbeck	Pharmacy Technician	Y
5	Christopher Marks	Pharmacy Technician	Y
6	Leon Salahuddein	Pharmacy Technician	Y
7	Blake Winterbower	Fulfillment Specialist/Clerk	N/A
8	Adam Norman	Fulfillment Specialist/Clerk	N/A
9	N/A	N/A	N/A
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
California Board of Pharmacy	Quality Drug Clinical Care	Retail Pharmacy/PHY 58254	7/1/2023
US DOJ/DEA	Quality Drug Clinical Care	Controlled Substances/FQ7438965	4/30/2024
N/A	N/A	N/A	N/A

Inspector Notes: Non-resident licenses held in: AZ, WI. Pharmacy is in the process of applying for AR. This is a pharmacy that dispenses HIV and related medications to approximately 450 HIV patients enrolled in LA Care and MediCal programs (they call the retail side), and specialty medications (including MS, oncology, HIV, dermatology, RA) to insured and MediCal patients (they call the specialty side). The pharmacy has been at this location in a commercial business center approximately five years, and was purchased by Lumicera in July 2021. There are a few HIV patients who come to the pharmacy to pick up their medications but the majority of prescriptions are shipped out.

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Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
Doc01_GP16_Quality Drug Clinical Care_Irvine CA	Four page CA BOP inspection report.
Doc02_GP57_Quality Drug Clinical Care_Irvine CA	Eleven pages for most recent two DEA biennial inventories.

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	X
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy	X (occasional pets of HIV patients)	Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	
HMO/PBM only		Nonsterile Hazardous Drug Compounding	
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	3500	Total Pharmacists:	4
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists	N/A
Nonsterile Compounding powder hoods number:	N/A	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Student Interns:	0
Nonsterile HD Compounding BSC/CACI hoods number:	N/A	Total Technicians:	4
Sterile Compounding Ante Room size:	N/A	Number of Compounding Technicians	N/A
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are certified?	1
Sterile Compounding Number LAFW hoods/areas:	N/A	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	N/A	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	N/A	Total Other Unlicensed Personnel:	2
Negative Pressure Sterile HD Room size:	N/A	Ratio #tech:#RPh present at time of inspection:	2:1
Sterile HD Compounding Number of BSC hoods:	N/A	Total Pharmacist Hours Per Week:	112
Sterile HD Compounding Number of CACI hoods:	N/A	Total Technician Hours Per Week:	150

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	120-150	Total Orders Distributed/day:	0
% Veterinary Prescriptions	<<0.1%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	9%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	<10% (chemotherapy)	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	0	0	March 2023
Alaska (AK)	0	0	March 2023
Arizona (AZ)	6	0	March 2023
Arkansas (AR)	0	0	March 2023
California (CA)	2203	0	March 2023
Colorado (CO)	0	0	March 2023
Connecticut (CT)	0	0	March 2023
Delaware (DE)	0	0	March 2023
District of Columbia (DC)	0	0	March 2023
Florida (FL)	0	0	March 2023
Georgia (GA)	0	0	March 2023
Hawaii (HI)	0	0	March 2023
Idaho (ID)	0	0	March 2023
Illinois (IL)	0	0	March 2023
Indiana (IN)	0	0	March 2023
Iowa (IA)	0	0	March 2023
Kansas (KS)	0	0	March 2023
Kentucky (KY)	0	0	March 2023
Louisiana (LA)	0	0	March 2023
Maine (ME)	0	0	March 2023
Maryland (MD)	0	0	March 2023
Massachusetts (MA)	0	0	March 2023
Michigan (MI)	0	0	March 2023
Minnesota (MN)	0	0	March 2023
Mississippi (MS)	0	0	March 2023
Missouri (MO)	0	0	March 2023
Montana (MT)	0	0	March 2023

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	0	0	March 2023
Nevada (NV)	0	0	March 2023
New Hampshire (NH)	0	0	March 2023
New Jersey (NJ)	0	0	March 2023
New Mexico (NM)	0	0	March 2023
New York (NY)	0	0	March 2023
North Carolina (NC)	0	0	March 2023
North Dakota (ND)	0	0	March 2023
Ohio (OH)	0	0	March 2023
Oklahoma (OK)	0	0	March 2023
Oregon (OR)	0	0	March 2023
Pennsylvania (PA)	0	0	March 2023
Rhode Island (RI)	0	0	March 2023
South Carolina (SC)	0	0	March 2023
South Dakota (SD)	0	0	March 2023
Tennessee (TN)	0	0	March 2023
Texas (TX)	0	0	March 2023
Utah (UT)	0	0	March 2023
Vermont (VT)	0	0	March 2023
Virginia (VA)	0	0	March 2023
Washington (WA)	0	0	March 2023
West Virginia (WV)	0	0	March 2023
Wisconsin (WI)	0	0	March 2023
Wyoming (WY)	0	0	March 2023
Other:	N/A	N/A	N/A

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40 hours/week
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	The pharmacy sends out a text message to patients, who opt-in for that service, asking if they want to refill their medication. Patients can reply with a 'yes'.
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**	[redacted]	The following corporate level personnel provided PIC Zapart information via email during the inspection: Peter Nielson, RPh, Dir of New Business Operations, and Jennifer Morrison, Assoc Dir of Quality and Development.
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	<<0.1% Patient specific Cabenuva and bicillin are sent to a CA provider for patient administration, about 2-10 per month. Sent via courier. These items do not require reconstitution or further manipulation prior to administration. None sent to other states.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide detoils such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	No routine inspection schedule. Last visit 7/20/2021 at time of change of ownership. See attached copy of the inspection report. Doc01_GP16_Quality Drug Clinical Care_Irvine CA.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Order of Correction to maintain all required CS inventories per CA rules and regs.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state ond the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restrictian.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the ogency ond additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the phormocy is inspected/visited by the DEA.*	No	

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC Specialty 3.1 effective 6/1/2020 - 6/1/2023. Date of survey not obtained.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	No	Kept electronically, stored on the cloud at least 10 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	No	Verbal prescriptions are reduced to writing then written Rxs are scanned electronically into the computer database and stored on the cloud.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	No	Kept electronically, stored on the cloud at least 10 years.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	No	Dispensing records maintained electronically in the computer database and stored to the cloud at least 10 years
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	The computer databases prevent deletion of any records. Records stored electronically on the cloud for at least 10 years.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	Yes	Some old paper records were sent to Lumicera HQ in WI for secure long term storage. Cloud storage requires password for access.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	P&P statement that RPh will always comply with all state and federal laws.

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Personnel bring a hard copy of their license, which is copied and downloaded into the computer system.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Corporate keeps an eye on licenses and sends an email to the PIC with a reminder of upcoming staff expiring licenses.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certificatians and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the moximum number of staff who work at the same time.*	Yes	Use no less than 2:1 and sometimes staff 1:1. At times staff as many as 7 RPh and PT at the same time.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Cox Security. Motion sensors, cameras inside, contact sensors on doors, community cameras outside. Key lock and alarm code at doors for entry and exit at open/close, held only with RPhs. Cameras available on cell phone of PIC and corporate has access to interior cameras.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	Locked in a keyed safe, keys only with RPh. Only opened at time of accessing to obtain drugs for immediate dispensing, then locked again.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	PIC would be notified and would stay on site until the building could be secured by the landlord. Corporate notified. If severe damage, the PIC and corporate would determine how and where to move drug inventory.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	

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		Finding	Notes
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Send to RD: Pharmalink
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Picked up by Medical Waste Disposal who come quarterly.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Utilize the PIC's office, if needed. Only minimal Rx's picked up at the pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Unknown	Two roof mounted HVAC systems to facility. Maintenance overseen by landlord: Irvine Company. Irvine Co sets the thermostats with a set range of 68°F-77°F 24/7. Pharmacy staff cannot adjust a thermostat. There is a small digital thermometer magnetically attached to a centrally located post inside the pharmacy with a readout for current temperature and humidity with min/max readings, however the min/max readings are never reset. This thermometer is not calibrated. Current temperature reading was 23.4°C. Temperature is not written on a log. The humidity is recorded on a written log for the min/max reading of 15%/71%. If the HVAC were to go down the landlord would notify the PIC.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	No	No CRT temperatures maintained. The landlord would notify the pharmacy if there was an HVAC failure, or if temperatures fall outside 68°F-77°F.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	No	No excursion action plan for drugs stored in CRT space, would use clinical judgement at the time of an issue.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Unknown	PIC states the refrigerators are monitored 24/7 via Dickson probes in four refrigerators. (A new fifth refrigerator, delivered in recent weeks, is awaiting a new probe and for now is used only to place a few items during the day awaiting shipment.) The Dickson probes are located on top of the refrigerators and are unable to be retrieved to see readings. The pharmacy does not have access to the electronic Dickson records, so unable to determine current temperatures and history of excursions. Per the PIC the range is set at 36°F-46°F. Temperatures are monitored by Dickson who have a phone call tree of pharmacist staff to notify for excursions. On four refrigerators there are built in thermometers with digital readouts. One refrigerator has a manual thermometer located inside. These thermometers are not calibrated. Temperatures from the refrigerators' built-in thermometers and manual thermometer are written on a log twice daily. The written logs are maintained for at least 10 years. Staff rely on phone calls from Dickson, after hours, for excursions. If no call assumed to be within range. Dickson probes are calibrated quarterly by Norm's refrigeration who are under contract to provide services. It is unknown if the electronic Dickson probe readings are maintained.

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		Finding	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	No	Five refrigerators, per the written logs: 35°F, 36°F, 36°F, 38°F, 35°F. Review of the written logs find that refrigerators appear to be routinely measured at 35°F. Four of the refrigerators have documented temperatures on the written logs in the 34°F-35°F at multiple times throughout recent months. The finding of the various low temperature readings were pointed out to the PIC during the inspection. The inspector's scans of the logs during the inspection apparently did not get saved for attachment to this report. There was no action by staff for the refrigerator temperature readings.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen items at the facility. Freezers hold only ice packs.
42.01	Is the temperature in the freezer within the USP range (between -25° to -10°C or -13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	A gasoline portable generator on location would provide electricity to refrigerators, computers and lights. Requires staff to go to the gas station to obtain gasoline to run the generator during a power outage. For a refrigerator failure, drug items would be moved to a working refrigerator at the pharmacy.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Landlord is responsible to obtain repairs.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	No	Would use clinical judgement at the time of an issue.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	No	The pharmacy can purchase only from sources approved by Lumicera and within the computer database.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	Some come from WDs.
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
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		Finding	Notes
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	McKesson, Cardinal, AmerisourceBergen, Anda, Hercules, Keysource. These are primary WDs that purchase only from MFRs, per Lumicera P&Ps.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	The sources are verified and approved by Lumicera. The sources are in the computer and the pharmacy can only order from these vendors.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for phormacies in the supply choin?)*	No	Per Lumicera policy and their corporate vetting process. Pharmacy personnel do not review transaction data for items they purchase. Ordering/invoice documents observed during the inspection included direct purchase statements.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	This is preprogrammed by corporate within the Lumicera computer database system and is not tracked by the pharmacy.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	Per corporate and not handled by the pharmacy.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	No	PIC would seek guidance from their corporate supervisor.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchoses to determine if the pharmacy is receiving and mointaining 3T data for o minimum of 6 years.*	No	The pharmacy is not involved with review of this information and relies on corporate to maintain oversight of transaction data.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	No	Per corporate and not handled by the pharmacy.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	PIC has sole POA for the pharmacy.

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		Finding	Notes
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or poper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Full monthly inventory checks for specialty items. Computer system maintains perpetual inventory.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	BOP and law enforcement.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetuol log and verify that reconciliation is taking place.*	Yes	CII's counted with every receiving and dispensing, and documented in the log book. A label for each CII Rx is affixed to the log book. Full quarterly inventories.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the lost inventary and frequency taken (minimum every two years).*	Yes	Most recent biennial inventory 12/30/2022. Officially performed every two years. See attached inventory reports. Doc02_GP57_Quality Drug Clinical Care_Irvine CA.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the ather states.*	N/A	

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		Finding	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Segregated in a quarantine area. Quarterly checks for outdates and during dispensing. Expiration dates are written in large sharpie on the outside of the bottle of opened containers.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	No outdated items identified during spot check of current inventory.
60.02	How often is active-stock examined for drugs past the expiration date?	[redacted]	Quarterly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	Yes	By patient request, the pharmacy will place a patient's pills into 'bingo-card' type bubble packs with multiple pills in one bubble. The cards contain patient specific Rx medication labels for each of the pills on the bubble card, affixed to the cardboard flap. The BUD used is the date on the individual Rx label based on the original stock bottle.
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	After 14 days.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	Label torn off, or patient name torn off label.
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Entered by RPh or PT at this facility. Updated with every monthly patient phone call. Patient calls made by RPh after verification of new and refilled Rxs.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Veterinary Rxs are occasionally dispensed and only for the companion animals of the regular HIV patients. The computer entry includes the first name of the pet and the last name of owner. Species is documented in the computer.

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		Finding	Notes
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	Due to the specialty nature of the drugs the pharmacy dispenses and the frequent patient contacts, patients are well known to the pharmacy. Insurance prior authorization (PA) is required for the majority of the drugs dispensed.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Contact the MD and the CA PMP (CURES). Rx30 has some internal checks and will automatically send messages for a suspicious situation.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Due to the specialty nature of the drugs the pharmacy dispenses and the frequent patient contacts, patients are well known to the pharmacy. Insurance prior authorization (PA)is required for the majority of the drugs dispensed.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	For the Rx30 database there is one RPh check at the last step of dispensing which includes checking the original Rx, drug identity and package details. Drugs are bar code scanned at time of pick. For the Rx Vector database, there is a PV1 after entry of the drug by the PT which includes checking the original Rx. PV2 occurs after labeling of the drug as a last step of dispensing and also includes comparison to original Rx. The checks are documented in the computer system.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	More severe interactions are triggered at the time of Rx entry and may require RPh bypasses at two different points in the dispensing process. DURs require RPh bypass and computer entry, or note at time of DUR review.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	No	Rx30 and Rx Vector did not have allergies listed or NKDA entered in profile. Rx Vector includes allergy info in the clinical assessment tab but that does not cross over to the DUR portion.

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		Finding	Notes
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Epocrates electronic database on the computer.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	CURES. Automatic upload from database to CURES. No CS sent out of state.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	RPh must override DURS with documentation captured in the computer.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan in Rx30 and Rx Vector.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	Any manual DUR or clinical information is typed into the patient counseling/communication/clinical assessment portions of the computer database.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	No manual veterinary compendia.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	Performed by the RPh with review of the original Rx, patient details in the computer, comparison to the packaging, bar code scan of the Rx and package, and documented in the computer.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Appropriate information including font size on labels.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	The pharmacy utilizes two computer dispensing databases, Rx30 for the 'retail' HIV side, and Rx Vector for the 'specialty' side. Rx Vector is a Lumicera proprietary system. Both systems are password protected, with access limited by RPh or PT licensure.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Paperwork with patient identifiers is shredded by Specialist Inc.

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		Finding	Notes
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	Utilize Rocket or Uline qualified shipping containers for refrigerated drugs to maintain temperatures for shipment. All refrigerated items shipped overnight only on Monday-Thursday. The required packaging instructions are noted on the shipping label to prompt pharmacy staff to utilize the appropriate packaging, Styrofoam, gel packs and paper. Twice a year Lumicera oversees a shipment with temperature probes that are then analyzed to ensure the package system and qualified containers are appropriate for temperature sensitive shipments.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Finding	Notes
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	The RPh calls each patient monthly after verification of new and refilled Rxs. This call includes patient and drug specific counseling.
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	No	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	The RPh calls each patient monthly after verification of new and refilled Rxs. This call includes patient and drug specific counseling.
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	No	
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	The RPh calls each patient monthly after verification of new and refilled Rxs. This call includes patient and drug specific counseling.
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	No	
78.00	Is patient counseling provided for delivered prescriptions? *Printed informotion sent to patient, toll-free number for potients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	The RPh calls each patient monthly after verification of new and refilled Rxs. This call includes patient and drug specific counseling.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to potient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	The RPh calls each patient monthly after verification of new and refilled Rxs. This call includes patient and drug specific counseling.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Print out automatically at the time of dispensing to include in the shipment.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Print out automatically at the time of dispensing to include in the shipment.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	Yes	Vigabatrin, bosentyn, ambrisentan, and brodalumab.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Within the computer database in tabs of the patient profile and dispensing section.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	An 'on-call' RPh carries the 'on-call' cell phone. These are Lumicera based RPh and are not just specific to this pharmacy. The 'on-call' RPh would not have access to this pharmacy's patient database and would only give general drug information. For emergencies they instruct the patient to call 911.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	This is a corporate program with information, processes and follow-up handled at corporate by corporate level personnel.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic.
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal troining or reviewed at a yearly meeting.*	Yes	Training on the CQI program is via the Lumicera training portal 'PALS'. Training will occur at hire and annually or as needed.
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentotion/forms are hard copy or electronic.*	Yes	Pharmacy staff enter the details of the QRE information electronically into the Lumicera portal as soon as the issue is identified.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	Review of the situation may include corporate personnel reviewing camera footage recorded in the dispensing area for the involved situation.
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Performed at corporate by corporate personnel. Frequency is unknown. Review and evaluation of the situation may include corporate personnel reviewing camera footage recorded in the dispensing area for the involved situation.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	N/A	Corporate would make changes to involved P&Ps, if necessary, and institute them at the pharmacy.
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	No	This process is at the corporate level. Quality issues are sent down to the pharmacy for review, as needed.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	N/A	

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Facility Name: Quality Drug Corporation dba Quality Drug Clinical Care
e-Profile ID: 1714080
Inspection Date: 4/20/2023

		Finding	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	N/A	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Unknown	This process is at the corporate level.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	Adverse events are reported to MedWatch.
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	The pharmacy does not handle these items.
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	No	The quality program is a corporate program.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Surveys come from corporate.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	Once a patient calls with a complaint, the staff enters the information into the Lumicera quality reporting portal to create a patient complaint entry.

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review
EMT	Emergency medical technician

EPA	Environmental Protection Agency
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement
QRE	Quality Related Event
RAM	Radioactive Material

RCRA	Resource Conservation and Recovery Act
REMS	Risk evaluation mitigation strategy
RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.
Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 10/20/2021 Inspector: Simin Samari

Firm: QUALITY DRUG CLINICAL CARE Phone: (949) 471-0223

Address: 18 TECHNOLOGY DR STE 104 City: IRVINE Zip: 92618

Ownership: CORPORATION

Permit #: PHY58254 Permit Exp: 12/15/2021 DEA#: FQ7438965 DEA Exp: 4/30/2024

Date of Self Assessment Form: 7/20/2021 Other Permit #: N/A Date of DEA Inventory: 12/9/2020

Hours M-F: 9AM-6PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC SEBASTIAN I ZAPART RPH59562 Administrator ___

RPH Consultant ___

Staff

RPH Name:	License #:	Staff Name:	License #:
LAUREL V HIPSZER	RPH71499	ADAM NORMAN	DRIVER
STEVEN T HARSHE	RPH47551	BLAKE WINTERBOWER	CLERK
		CHRISTIAN R CORTEZ	TCH75584
		CHRISTOPHER T BRODBEC	TCH146986
		LEON R SALAHUDDIN	TCH153792

Inspector Remarks:

Here to conduct a routine inspection. PIC Zapart is present and assisting with the inspection. The pharmacy had a change of ownership in July (2021 from PHY 55474) and is in the process of switching database and files from the previous owners to the new ownership. Also there are plans for remodeling of the pharmacy. The pharmacy specializes in HIV/AIDS medications and plans to deliver/ship specialty medications (MS, RA, Growth hormones, etc.) to the patients in California. The pharmacy also processes 340B medications for HIV population.

Type of pharmacy: Retail- pharmacy owned by Lumicera Health Services LLC. (as the main owner).
Website address: currently N/A
Board of Pharmacy Subscriber Email List: licensing@lumicera.com
-CURES: PIC receives email confirmation from AA
-NTC, premises' original license & its renewal, and DEA Registration: are posted in public view at the entrance.
-Pharmacy: Sink is equipped with Hot/Cold water, Restrooms are clean and have functioning sinks.
-Pharmacy area and drug storage shelves: are in the process of remodeling under the new ownership.
-Drug Storage Temperatures: Refrigerator Temperature (36-46F / 2-8C): 7C, tempretures is logged both manual and electronically. Range is noted on the log. Freezer (-25 to -10C, -13 to 14F): used for ice storage. Pharmacy is in the process of expanding and installing new refrigerators and freezers.

-Self Assessment(s): Reviewed, prior SA is on file. PIC completed one when new PHY permit was issued.

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-Policy & Procedures: available for:
Technician Job Description/Qualification
Theft/Impairment/Diversion
Temporary Absence of Pharmacist
Interpretive services (Point to your Language poster): poster is posted. Pharmacy has contracted TransPerfect Connect for translation.
Quality assurance as it relates to medication errors. PIC states there has been no errors since they have been open.
Controlled substances inventory reconciliation (1715.65(b) - will Provide.
Immunization (RPHs do not do flu or Covid). Barely do any and will stop immunization as soon as all the data is transferred to the new software (the new software does not support CAIR system).
-Controlled substances: CII are secured, accessed by pharmacists only. Perpetual log is utilized for CII medications. The pharmacy's database keeps real-time inventory.
-Invoices - Stores scheduled and dangerous drug invoices separately. CII invoices are stored separately from all other invoices.
-DEA 222: uses CSOS and reconciles it upon receipt of medications.
-DEA Inventory: reviewed, was dated and signed properly
-Power of Attorney: PIC is the only person who orders the CII medications.
-Quarterly CII Reconciliation (CCR 1715.65): in-place
-Prescriptions: Almost all are electronic. Spot-checked.
-Confirmation of medication delivery: RPHs on duty sign for delivery. PIC states UPS and FedEx deliveries are also signed by RPH.
-Security: reviewed
-Naloxone dispensing: by Rx only
-Sudafed sales: by Rx only
-Outdates: Quarantined
-Reverse Distributor: PharmaLink
-Name Tags: compliant
-Wholesaler(s): Bergen, KeySource, Anda
-Electronic Software: currently Rx30 and Rx Vector, but will only be Rx Vector once all the data is transmitted to it.
-Rx Label: medication descriptions, patient centered labeling: compliant
-Rx Label: Opioid warning: "Caution Risk of Overdose or addiction" (BPC 4076.7): compliant
-Consultation: done by phone mostly.
-Compounding: does not perform any compounding
-Disposal of confidential information: compliant

Discussion items:

-PIC to email his POA.

Simin Samari, Pharm D., Inspector
Sacramento, CA 95833
Phone: 949-337-0787
Email: simin.samari@dca.ca.gov

Education Topics/Reminders:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

-2021 Scripts are available on the Board's website.
• New CE requirements for RPH license renewal as of July 2019. CE Course – Ethics and Pharmacy Law Webinar. See www.pharmacy.ca.gov
• Licensee email addresses BPC 4013. December 2018 Script
• Drug Take Back CCR 1776 and registration forms and locations on website
• Naloxone education provided by Board BPC 4052.01/CCR 1746.3. See December 2018 Script. Naloxone – Protocol & Training Webinar – See www.pharmacy.ca.gov
• Routine Inspection Records Ready for Inspection. See June 2017 Script
• Diabetic Test Strips BPC 4025.2 BPC 4081d. See Oct 2017 Script p 9
-Pre and post HIV exposure medication order (SB 159)
-Opioid warning Label (SB 1109/BPC 4076.7)
-Inventory reconciliations (CCR 1715.65)
-Secure Prescription form Serial Number (HSC 11162.2)
-Consultation requirements for delivery or mail order prescriptions (CCR 1707.2)
-Community Pharmacy Staffing (CCR 1714.3)/(4113.5)

Licensee Remarks:

I have reviewed, discussed, understand and received a copy of this form.

Pharmacist (sign) _____
Pharmacist (print) Sebastian Zapart

Inspector (sign) _____
Inspector (print) Simin Samaan

Owner(sign) _____
Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 10/20/2021 Permit #: PHY58254

Time of Day: 11:03 AM

Name as shown on permit: **QUALITY DRUG CLINICAL CARE**

Address: 18 TECHNOLOGY DR STE 104 City: IRVINE

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. CCR 1715.65(b) Inventory Reconciliation Report of Controlled Substances. The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

PiC to provide a copy of the P&P by 10/31/21.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) [signature]

Inspector (print) Simin Samaan

Date 10-20-2021

Signed [signature]

Print Name Sebastian Lagant

Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

Biennial Caltron Inv 12/9/20

QUALITY DRUG CLINICAL CARE
18 Technology Drive
Irvine, CA 92618
(949) 471-0223

DRUG INVENTORY REPORT LISTING
Drug Inventory Summary by DEA Class
Wed Dec 9, 2020

End of day

PID: 5666132
NPI: 1417453226

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO	QTY/RO	OBS PT	340B PRI	MAC SCH1/PRI	AWP- SCH2/PRI	COST SCH3	VENDOR NAME
ACETAMINOPHEN-COD #3 TABLET		3	MALLINCKRO	100.000	TAB	5	6	N	N	$0.1134	$0.6140	$0.1449	
0406-0484-01	137450	N	502127	Rx Gen	300-30		0/	0	AWP				AMERISOURCE
ADDERALL XR 10MG CAP		2	SHIRE US	100.000	CAP	✓	30	N	N	$7.4950	$8.5475	$6.8630	
54092-383-01	126589	N	502565	Rx Brd	10		0/	0	AWP				AMERISOURCE
ADDERALL XR 15MG CAP		2	SHIRE US	100.000	CAP	✓	50	N	N	$6.2055	$8.5475	$6.8630	
54092-385-01	557342	N	502566	Rx Brd	15		0/	0	AWP				AMERISOURCE
ADDERALL XR 20MG CAPSULES		2	SHIRE US	100.000	CAP	✓	74	N	N	$6.6203	$8.5475	$6.8630	
54092-387-01	126560	N	502567	Rx Brd	20		0/	0	AWP				AMERISOURCE
ADDERALL XR 30MG CAP		2	SHIRE US	100.000	CAP	✓	7	N	N	$6.6067	$8.5475	$6.8630	
54092-391-01	126577	N	502569	Rx Brd	30		0/	0	AWP				AMERISOURCE
ADDERALL XR 5MG CAP		2	SHIRE US	100.000	CAP	✓	90	N	N	$6.3499	$8.5475	$6.8630	
54092-381-01	557335	N	502564	Rx Brd	5		0/	0	AWP				AMERISOURCE
ALPRAZOLAM 0.25 MG TABS		4	BRENCKRDG	500.000	TAB	✓	440	N	N	$0.0325	$0.6604	$0.0327	
51991-704-05	898546	N	500379	Rx Gen	0.25		0/	0	AWP				AMERISOURCE
ALPRAZOLAM 0.5 MG TABS		4	BRENCKRDG	1000.000	TAB	✓	754	N	N	$0.0449	$0.8228	$0.0353	
51991-705-10	900288	N	500385	Rx Gen	0.5		0/	0	AWP	AWP			AMERISOURCE
ALPRAZOLAM 1 MG TABS		4	BRENCKRDG	500.000	TAB	✓	320	N	N	$0.0778	$1.0978	$0.0404	
51991-706-05	898155	N	500396	Rx Gen	1		0/	0	AWP				AMERISOURCE
ALPRAZOLAM 2 MG TABS		4	BRENCKRDG	100.000	TAB	✓	80	N	N	$0.2054	$1.9156	$0.0964	
51991-707-01	898379	N	500397	Rx Gen	2		0/	0	AWP				AMERISOURCE
ALPRAZOLAM 2MG TAB		4	ACTAV ELIZ	100.000	TAB	✓	14	N	N	$0.2054	$1.9645	$0.1755	
0228-2039-10	309641	N	500397	Rx Gen	2		0/	0	AWP				AMERISOURCE
AMPHET-DEXTRO 30MG ER CAPS		2	AMERIGEN P	100.000	CAP	✓	70	N	N	$6.6067	$1.6680	$0.5063	
43975-336-10	819946	N	502569	Rx Gen	30		0/	0	Fixed Retail Price: 33 for $610.00				
AMPHETAMINE SALTS 10MG TAB		2	SANDOZ	100.000	TAB	✓	6	N	N	$0.3186	$1.7140	$0.3791	
0185-0842-01	541144	N	503193	Rx Gen	10		0/	0	AWP				AMERISOURCE
AMPHETAMINE SALTS 20MG TAB		2	TEVA USA	100.000	TAB	✓	37	N	N	$0.4171	$1.7140	$0.4465	
0555-0973-02	317279	N	503204	Rx Gen	20		0/	0	AWP				AMERISOURCE
AMPHETAMINE SALTS 30MG TABS		2	TEVA USA	100.000	TAB	✓	91	N	N	$0.4055	$1.7140	$0.6255	
0555-0974-02	317293	N	503205	Rx Gen	30		0/	0	AWP				AMERISOURCE
AMPHETAMINE SALTS 5MG TAB		2	TEVA USA	100.000	TAB	✓	50	N	N	$0.3634	$1.7140	$0.5025	
0555-0971-02	317250	N	503192	Rx Gen	5		0/	0	AWP				AMERISOURCE
BELSOMRA 20MG TABLET		4	MERCKSHARP	30.000	TAB	✓	9	N	N	$0.0000	$14.6280	$11.7453	
0006-0335-30	365353	N	500225	Rx Brd	20		0/	0	AWP				AMERISOURCE
BUPRENORPHIN-NALOXON 8-2 MG		3	WEST-WARD	30.000	TAB	✓	50	N	N	$1.3035	$10.4213	$0.9610	
0054-0189-13	504987	N	501052	Rx Gen	8-2		0/	0	AWP				AMERISOURCE
BUPRENORPHINE 2 MG TAB SL		3	SUN PHARMA	30.000	TAB	✓	19	N	N	$0.5367	$4.5000	$0.5757	
62756-459-83	634113	N	501049	Rx Gen	2		0/	0	AWP				AMERISOURCE
BUPRENORPHINE 8MG SUBL TABS		3	SUN PHARMA	30.000	TAB	✓	32	N	N	$0.9539	$8.4600	$1.3730	
62756-460-83	634089	N	501050	Rx Gen	8		0/	0	AWP				AMERISOURCE
BUPRENORPHINE HCL 2 MG SUBL		3	RHODES PHA	30.000	TAB	✓	30	N	N	$0.5367	$4.4347	$0.5330	
42858-501-03	713755	N	501048	Rx Gen	2		0/	0	AWP				AMERISOURCE
BUPRENORPHINE HCL-NALOXONE		3	MYLAN	30.000	FILM	✓	48	N	N	$0.0000	$9.2293	$5.8390	
0378-8767-93	849758	N	507544	Rx Gen	8-2		0/	0	AWP				AMERISOURCE
BUPRENORPHINE-NALOX 4/1MG		3	DR.REDDY'S	30.000	FILM	✓	2	N	N	$0.0000	$8.8000	$5.3357	
43598-580-30	849822	N	507543	Rx Gen	4-1		0/	0	DEFAULT				AMERISOURCE
BUPRENORPHINE/NALOXONE 2/.5		3	SANDOZ	30.000	FILM	✓	12	N	N	$0.0000	$5.1170	$3.3617	
0781-7216-54	764720	N	507542	Rx Gen	2-0.5		0/	0	AWP				AMERISOURCE
BUPRENORPHINE/NALOXONE 8/2M		3	ALVOGEN	30.000	FILM	✓	1	N	N	$0.0000	$8.7900	$7.4100	
47781-357-03	850875	N	507544	Rx Gen	8-2		0/	0	AWP				AMERISOURCE

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PID: 5666132
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DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO QTY	OBS RO	PT	340B PRI	MAC SCH1/PRI	AWP SCH2/PRI	SCH3	COST VENDOR NAME
BUPRENORPHN-NALOXN 2-0.5 MG		3	WEST-WARD	30.000	TAB	78	N		N	$0.9205	$5.8257		$1.1847
0054-0188-13	356840	N	501051	Rx Gen	2-0.5	0/		0	AWP				AMERISOURCE
BUT/ASA/CAF 50/325/40MG CAP		3	ACTAVIS PH	100.000	CAP	20	N		N	$0.0000	$1.6998		$0.9307
0591-3219-01	904108	N	505130	Rx Gen	50-325-40	0/		0	AWP				AMERISOURCE
CARISOPRODOL 350 MG TABS		4	OXFORD PHA	100.000	TAB	90	N		N	$0.0908	$0.5963		$0.0687
69584-111-10	984000	N	500764	Rx Gen	350	0/		0	AWP				AMERISOURCE
CHLORDIAZEPOXIDE 25MG CAP		4	TEVA USA	100.000	CAP	88	N		N	$0.0000	$0.4284		$0.0747
0555-0159-02	759613	N	504869	Rx Gen	25	0/		0	AWP				AMERISOURCE
CLONAZEPAM 0.25MG ODT TABS		4	SUN PHARMA	60.000	TAB	30	N		N	$0.6834	$1.2988		$0.4833
57664-784-86	691016	N	505220	Rx Gen	0.25	0/		0	AWP				AMERISOURCE
CLONAZEPAM 0.5MG TAB		4	TEVA USA	500.000	TAB	190	N		N	$0.0404	$0.7490		$0.0272
0093-0832-05	907584	N	500144	Rx Gen	0.5	0/		0	AWP				AMERISOURCE
CLONAZEPAM 2 MG TABS		4	TEVA USA	100.000	TAB	70	N		N	$0.0683	$1.1841		$0.0365
0093-3213-01	916991	N	500146	Rx Gen	2	0/		0	AWP				AMERISOURCE
D-AMPHETAMINE ER 15 MG CAP		2	MALLINCKRO	100.000	CAP	90	N		N	$8.2209	$6.5410		$1.9200
0406-8962-01	818599	N	504164	Rx Gen	15	0/		0	AWP				AMERISOURCE
DEXMETHYLPHEN ER 15MG CAPS		2	SANDOZ	100.000	CAP	40	N		N	$4.9605	$7.7063		$3.5803
0781-2684-01	261730	N	501865	Rx Gen	15	0/		0	AWP				AMERISOURCE
DEXMETHYLPHENIDATE 5 MG TAB		2	KVK TECH	100.000	TAB	150	N		N	$0.2835	$0.9738		$0.1966
10702-107-01	494789	N	501811	Rx Gen	5	0/		0	AWP				AMERISOURCE
DEXTRO-AMPHET 15MG TABLETS		2	TEVA USA	100.000	TAB	40	N		N	$0.3419	$1.7140		$0.5000
0555-0777-02	721757	N	503457	Rx Gen	15	0/		0	AWP				AMERISOURCE
DEXTRO-AMPHET 20MG ER CAPS		2	RHODES PHA	100.000	CAP	86	N		N	$6.6203	$4.5415		$0.7020
42858-720-01	905109	N	502567	Rx Gen	20	0/		0	AWP				AMERISOURCE
DEXTRO-AMPHET ER 10MG CAPS		2	RHODES PHA	100.000	CAP	6	N		N	$7.4950	$4.5415		$0.7020
42858-610-01	905141	N	502565	Rx Gen	10	0/		0	AWP				AMERISOURCE
DEXTRO/AMPHET 25MG ER CAPS		2	RHODES PHA	100.000	CAP	30	N		N	$6.6769	$4.5415		$0.7020
42858-325-01	905166	N	502568	Rx Gen	25	0/		0	AWP				AMERISOURCE
DEXTROAMP-AMP ER 15MG CAP		2	SANDOZ	100.000	CAP	90	N		N	$6.2055	$6.1315		$2.6755
0781-2343-01	561035	N	502566	Rx Gen	15	0/		0	AWP				AMERISOURCE
DEXTROAMP-AMPHET 10MG TABS		2	MALLINCKRO	100.000	TAB	60	N		N	$0.3186	$1.7140		$0.5516
0406-8892-01	323212	N	503193	Rx Gen	10	0/		0	AWP				AMERISOURCE
DIAZEPAM 10 MG TABS		4	MAYNE PHAR	100.000	TAB	7	N		N	$0.2016	$0.4219		$0.1909
51862-943-01	935458	N	502726	Rx Gen	10	0/		0	AWP				AMERISOURCE
DIAZEPAM 10MG TAB		4	MYLAN	500.000	TAB	591	N		N	$0.2016	$0.2969		$0.0908
0378-0477-05	460121	N	502726	Rx Gen	10	0/		0	AWP				AMERISOURCE
DIAZEPAM 5 MG TABS		4	MAYNE PHAR	100.000	TAB	7	N		N	$0.1313	$0.2201		$0.1469
51862-063-01	566331	N	502725	Rx Gen	5	0/		0	Fixed Retail Price: 16 for		$25.00		
DIAZEPAM 5MG TAB		4	MYLAN	500.000	TAB	428	N		N	$0.1313	$0.1468		$0.0449
0378-0345-05	459529	N	502725	Rx Gen	5	0/		0	AWP				AMERISOURCE
DIPHENOXYLATE-ATROP 2.5-0.0		5	ANI PHARMA	100.000	TAB	281	N		N	$0.2263	$0.7000		$0.2950
62559-490-01	680959	N	500653	Rx Gen	2.5-0.025	0/		0	AWP				AMERISOURCE
DRONABINOL 5 MG CAPS		3	RHODES PHA	60.000	CAP	30	N		N	$2.6467	$4.2202		$3.3420
42858-868-06	755678	N	500956	Rx Gen	5	0/		0	AWP				AMERISOURCE
ESTROGEN-METHYLTESTOS H.S.		3	ANI PHARMACE	100.000	TAB	100	N		N	$0.0000	$0.0000		$1.5860
62559-0150-01	226969	N	506621	Rx Gen	0.625-1.25	0/		0					AMERISOURCE
ESZOPICLONE 1 MG TABS		4	GLENMARK	100.000	TAB	55	N		N	$0.2371	$12.1477		$0.1612
68462-382-01	295501	N	501086	Rx Gen	1	0/		0	AWP				AMERISOURCE
ESZOPICLONE 2 MG TABLET		4	GLENMARK	100.000	TAB	45	N		N	$0.2760	$12.1477		$0.1796
68462-383-01	295530	N	501087	Rx Gen	2	0/		0	AWP				AMERISOURCE

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ESZOPICLONE 3 MG TABS		4	GLENMARK	100.000	TAB	121	N	N		$0.6402	$12.1477	$0.1481	
68462-384-01	295543	N	501088	Rx Gen	3	0/		0	AWP				AMERISOURCE
FENTANYL 25 MCG/HR PATCH		2	MALLINCKRO	5.000	PTCH	15	N	N		$3.4815	$14.4200	$3.7280	
0406-9025-76	086518	N	503501	Rx Gen	25	0/		0	AWP				AMERISOURCE
FOCALIN 10MG TAB		2	NOVARTIS	100.000	TAB	20	N	N		$0.3997	$1.5565	$1.2498	
0078-0382-05	298099	N	501812	Rx Brd	10	0/		0	AWP				AMERISOURCE
HYDROCODON-APAP 10-325		2	MALLINCKRO	100.000	TAB	122	N	N		$0.1437	$0.9564	$0.0935	
0406-0125-01	350470	N	503128	Rx Gen	10-325	0/		0	AWP				AMERISOURCE
HYDROCODON-APAP 10-325		2	TRIS PHARM	100.000	TAB	10	N	N		$0.1437	$0.9564	$0.1206	
27808-037-01	520306	N	503128	Rx Gen	10-325	0/		0	AWP				AMERISOURCE
HYDROCODON-APAP 5-325		2	MALLINCKRO	100.000	TAB	138	N	N		$0.1067	$0.6915	$0.1509	
0406-0123-01	350431	N	503127	Rx Gen	5-325	0/		0	AWP				AMERISOURCE
HYDROCODON-APAP 7.5/325 TAB		2	MALLINCKRO	100.000	TAB	37	N	N		$0.1449	$0.7702	$0.0928	
0406-0124-01	350447	N	504536	Rx Gen	7.5-325	0/		0	AWP				AMERISOURCE
HYDROMORPHONE 2MG TAB		2	MALLINCKRO	100.000	TAB	80	N	N		$0.0927	$0.4804	$0.1301	
0406-3243-01	391532	N	504564	Rx Gen	2	0/		0	AWP				AMERISOURCE
KETAMINE HCL 50 MG/ML SOLN		3	HIKMA	10.000	SOLN	80	N	N		$0.0000	$0.6990	$0.5534	
0143-9508-10	597294	N	502774	Rx Gen	50	0/		0	Fixed Retail Price: 10 for $29.99				
LOMOTIL 2.5MG TAB		5	PFIZER US	100.000	TAB	80	N	N		$0.2263	$3.3925	$2.7706	
0025-0061-31	256172	N	500653	Rx Brd	2.5-0.025	0/		0	AWP				AMERISOURCE
LORAZEPAM 0.5 MG TABS		4	LEADING PH	100.000	TAB	25	N	N		$0.1849	$0.6431	$0.0877	
69315-904-01	532729	N	502299	Rx Gen	0.5	0/		0	AWP				AMERISOURCE
LORAZEPAM 0.5MG TAB		4	ACTAVIS PH	100.000	TAB	213	N	N		$0.1849	$0.6431	$0.0288	
0591-0240-01	421321	N	502299	Rx Gen	0.5	0/		0	AWP				AMERISOURCE
LORAZEPAM 1MG TAB		4	ACTAVIS PH	100.000	TAB	211	N	N		$0.0540	$0.8800	$0.0494	
0591-0241-01	421370	N	502300	Rx Gen	1	0/		0	AWP				AMERISOURCE
LORAZEPAM 2 MG TABS		4	MAJOR	100.000	TAB	120	N	N		$1.0098	$0.0911	$0.0887	
0904-6009-60	445049	N	502301	Rx Gen	2	0/		0	AWP				AMERISOURCE
LORAZEPAM 2MG TAB		4	ACTAVIS PH	100.000	TAB	115	N	N		$1.0098	$1.2820	$0.0597	
0591-0242-01	421446	N	502301	Rx Gen	2	0/		0	AWP				AMERISOURCE
LYRICA 150MG CAP		5	PFIZER US	90.000	CAP	26	N	N		$0.6124	$9.8226	$7.8868	
0071-1016-68	539787	N	501608	Rx Brd	150	0/		0	AWP				AMERISOURCE
LYRICA 300MG CAPSULE		5	PFIZER US	90.000	CAP	109	N	N		$0.8573	$9.8226	$7.8868	
0071-1018-68	539902	N	501610	Rx Brd	300	0/		0	AWP				AMERISOURCE
LYRICA 75MG CAP		5	PFIZER US	90.000	CAP	78	N	N		$0.3824	$9.8226	$7.8868	
0071-1014-68	538640	N	501606	Rx Brd	75	0/		0	AWP				AMERISOURCE
METHADONE 10MG TAB		2	MALLINCKRO	100.000	TAB	8	N	N		$0.0957	$0.5294	$0.1052	
0406-5771-01	008370	N	501176	Rx Gen	10	0/		0	AWP				AMERISOURCE
METHADONE 10MG TAB		2	HIKMA	100.000	TAB	105	N	N		$0.0957	$0.4422	$0.2512	
0054-4571-25	650663	N	501176	Rx Gen	10	0/		0	AWP				AMERISOURCE
METHYLPHEN 27MG ER TABLETS		2	CAMBER PHA	100.000	TAB	93	N	N		$6.3788	$13.5403	$1.4202	
31722-953-01	908792	N	504354	Rx Gen	27	0/		0	AWP				AMERISOURCE
METHYLPHEN ER 18MG TABLETS		2	CAMBER PHA	100.000	TAB	93	N	N		$6.4389	$13.2092	$1.3736	
31722-952-01	908822	N	504353	Rx Gen	18	0/		0	AWP				AMERISOURCE
METHYLPHENIDATE ER 36MG TAB		2	PATRIOT PH	100.000	TAB	10	N	N		$7.1873	$9.8770	$5.4819	
10147-0686-1	846459	N	504355	Rx Gen	36	0/		0	AWP				AMERISOURCE
METHYLPHENIDATE ER 54 MG TA		2	ACTAVIS PH	100.000	TAB	30	Y	N		$7.5977	$11.1950	$10.4783	
0591-2718-01	113821	N	504356	Rx Gen	54	0/		0	AWP				AMERISOURCE
MODAFINIL 100 MG TABS		4	APOTEX	30.000	TAB	15	N	N		$0.4713	$26.3767	$0.6213	
60505-2526-3	323927	N	504207	Rx Gen	100	0/		0	AWP				AMERISOURCE

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MORPHINE SULF ER 15MG TABS		2	MALLINCKRO	100.000	TAB	✓	61	N		N	$0.2086	$1.6757	$0.2050	
0406-8315-01	851081	N	503471	Rx Gen	15		0/		0	AWP				AMERISOURCE
MYDAYIS 37.5 MG CAP		2	SHIRE US	100.000	CAP	✓	70	N		N	$0.0000	$11.7076	$9.4002	
54092-474-01	678122	N	514826	Rx Brd	37.5		0/		0	AWP				AMERISOURCE
OPIUM TINCTURE 10 MG/ML		2	EDENBRIDGE	118.000	TINC	✓	103	N		N	$0.0000	$6.2812	$2.7966	
42799-217-01	021814	N	503315	Rx Gen	10 MG/ML		0/		0	AWP				AMERISOURCE
OXYCODON-ACETAMINOPHEN 7.5-		2	AMNEAL	100.000	TAB	✓	5	N		N	$0.3023	$2.7154	$0.3922	
65162-207-10	468734	N	503453	Rx Gen	7.5-325		0/		0	AWP				AMERISOURCE
OXYCODON-APAP 7.5-325MG TAB		2	RHODES PHA	100.000	TAB	✓	26	N		N	$0.3023	$2.7154	$0.1903	
42858-103-01	348829	N	503453	Rx Gen	7.5-325		0/		0	AWP				AMERISOURCE
OXYCODONE 10MG TABLETS		2	RHODES PHA	100.000	TAB	✓	80	N		N	$0.1459	$0.1482	$0.1172	
42858-002-01	341711	N	505436	Rx Gen	10		0/		0	AWP				AMERISOURCE
OXYCODONE 30MG TABLET		2	KVK TECH	100.000	TAB	✓	10	N		N	$0.2622	$3.5893	$0.3999	
10702-009-01	030577	N	503450	Rx Gen	30		0/		0	AWP				AMERISOURCE
OXYCODONE 30MG TABLETS		2	MALLINCKRO	100.000	TAB	✓	60	N		N	$0.2622	$3.5893	$0.2718	
0406-8530-01	529711	N	503450	Rx Gen	30		0/		0	AWP				AMERISOURCE
OXYCODONE ER 20MG TABLETS		2	TEVA USA	100.000	TAB	✓	80	N		N	$0.0000	$5.6383	$4.0708	
0093-5732-01	489542	N	502355	Rx Gen	20		0/		0	AWP				AMERISOURCE
OXYCODONE HCL 15 MG TABLET		2	KVK TECH	100.000	TAB	✓	73	N		N	$0.1383	$1.8940	$0.1845	
10702-008-01	030502	N	503449	Rx Gen	15		0/		0	AWP				AMERISOURCE
OXYCODONE HCL 20MG TABLET		2	KVK TECH	100.000	TAB	✓	59	N		N	$0.2837	$1.1030	$0.2749	
10702-057-01	030536	N	505437	Rx Gen	20		0/		0	AWP				AMERISOURCE
OXYCODONE HCL 5MG TABLETS		2	KVK TECH	100.000	TAB	✓	87	N		N	$0.1071	$0.5411	$0.1061	
10702-018-01	030445	N	503448	Rx Gen	5		0/		0	AWP				AMERISOURCE
OXYCODONE HCL ER 20 MG T12A		2	KVK TECH	100.000	TAB	✓	40	N		N	$0.0000	$7.8750	$6.2668	
10702-803-01	862918	N	502355	Rx Gen	20		0/		0	DEFAULT				AMERISOURCE
OXYCODONE-APAP 10/325MG TAB		2	CAMBER PHA	100.000	TAB	✓	83	N		N	$0.5311	$3.5508	$0.2356	
31722-951-01	932079	N	503454	Rx Gen	10-325		0/		0	AWP				AMERISOURCE
OXYCODONE-APAP 5-325MG TABS		2	RHODES PHA	100.000	TAB	✓	92	N		N	$0.2036	$1.3687	$0.0956	
42858-102-01	348789	N	501130	Rx Gen	5-325		0/		0	AWP				AMERISOURCE
OXYCONTIN 15 MG TABLET		2	PURDUE	100.000	TAB	✓	74	N		N	$0.0000	$7.4653	$5.9941	
59011-415-10	100964	N	502586	Rx Brd	15		0/		0	AWP				AMERISOURCE
OXYCONTIN 20 MG TABLET		2	PURDUE	100.000	TAB	✓	5	N		N	$0.0000	$9.4572	$7.5934	
59011-420-10	100974	N	502355	Rx Brd	20		0/		0	AWP				AMERISOURCE
OXYCONTIN 80MG		2	PURDUE	100.000	TAB	✓	26	N		N	$0.0000	$28.2622	$22.6922	
59011-480-10	101004	N	502357	Rx Brd	80		0/		0	AWP				AMERISOURCE
PHENDIMETRAZINE TARTRATE 35		3	VIRTUS PHA	100.000	TAB	✓	60	N		N	$0.1829	$0.3625	$0.1658	
69543-410-10	760124	N	503222	Rx Gen	35		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 16.2 MG TAB		4	E5 PHARMA	100.000	TAB	✓	99	N		N	$0.0000	$0.5307	$0.4253	
13517-110-01	642470	N	505440	Rx Gen	16.2		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 16.2 MG TABS		4	ECI PHARMA	100.000	TAB	✓	99	N		N	$0.0000	$0.5344	$0.3938	
51293-625-01	362835	N	505440	Rx Gen	16.2		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 30 MG TABS		4	ECI PHARMA	100.000	TAB	✓	49	N		N	$0.0000	$0.4224	$0.2975	
51293-692-01	996292	N	502751	Rx Gen	30		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 32.4 MG TAB		4	E5 PHARMA	100.000	TAB	✓	22	N		N	$0.0000	$0.6703	$0.6273	
13517-111-01	642456	N	505441	Rx Gen	32.4		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 64.8 MG TAB		4	E5 PHARMA	100.000	TAB	✓	32	N		N	$0.0000	$0.8379	$0.5260	
13517-112-01	642431	N	505442	Rx Gen	64.8		0/		0	AWP				AMERISOURCE
PHENOBARBITAL 64.8 MG TABS		4	ECI PHARMA	100.000	TAB	✓	6	N		N	$0.0000	$0.8438	$0.5537	
51293-627-01	362850	N	505442	Rx Gen	64.8		0/		0	AWP				AMERISOURCE

QUALITY DRUG CLINICAL CARE
18 Technology Drive
Irvine, CA 92618
(949) 471-0223

DRUG INVENTORY REPORT LISTING
Drug Inventory Summary by DEA Class
Wed Dec 9, 2020

PID: 5666132
NPI: 1417453226

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO	QTY/RO	PT	OBS PRI	340B PRI	MAC SCH1/PRI	AWP SCH2/PRI	COST SCH3	VENDOR NAME
PHENTERMINE 37.5 MG TABLET		4	KVK TECH	100.000	TAB	✓	70	N	N		$0.0871	$1.5425	$0.0812	
10702-025-01	629598	N	502213	Rx Gen	37.5		0/	0	AWP					AMERISOURCE
PREGABALIN 100 MG CAPS		5	DR.REDDY'S	90.000	CAP	✓	30	N	N		$0.4979	$8.4273	$0.1887	
43598-294-90		N	501607	Rx Gen	100		0/	0	Default					
PREGABALIN 200 MG CAPS		5	CIPLA USA	90.000	CAP	✓	240	N	N		$0.6817	$7.2863	$0.1666	
69097-959-05	887620	N	501609	Rx Gen	200		0/	0	AWP					AMERISOURCE
PREGABALIN 25 MG CAPS		5	CIPLA USA	90.000	CAP	✓	30	N	N		$0.3042	$7.1821	$0.1521	
69097-954-05	887594	N	501604	Rx Gen	25		0/	0	Default					AMERISOURCE
PREGABALIN 300 MG CAPS		5	DR.REDDY'S	90.000	CAP	✓	30	N	N		$0.8573	$8.4273	$0.2108	
43598-298-90	894360	N	501610	Rx Gen	300		0/	0	Default					AMERISOURCE
PROMETH W/COD 6.25/10MG/5ML		5	MURTON GRV	473.000	SOLN	✓	486	N	N		$0.0373	$0.0973	$0.0829	
60432-606-16	550566	N	504973	Rx Gen	6.25-10		0/	0	AWP					AMERISOURCE
SUBOXONE SUBL 8/2MG FILM		3	INDIVIOR	30.000	FILM	✓	24	N	N		$0.0000	$10.7760	$8.6523	
12496-1208-3	018549	N	507544	Rx Brd	8-2		0/	0	Fixed Retail Price: 6 for				$83.00	
TEMAZEPAM 15 MG CAPSULE		4	ASCENDLABS	100.000	CAP	✓	104	N	N		$0.1096	$0.8149	$0.0909	
67877-146-01	398382	N	503430	Rx Gen	15		0/	0	AWP					AMERISOURCE
TEMAZEPAM 30 MG CAPSULE		4	ASCENDLABS	500.000	CAP	✓	403	N	N		$0.1457	$0.9580	$0.1125	
67877-147-05	323915	N	503431	Rx Gen	30		0/	0	AWP					AMERISOURCE
TESTOSTERONE 1.62 % GEL		3	AMNEAL	75.000	GEL	✓	225	N	N		$6.3410	$8.9429	$0.6000	
69238-1013-2	886143	N	500962	Rx Gen	1.62		0/	0	AWP					AMERISOURCE
TESTOSTERONE 20.25 MG/ACT (		3	PERRIGO	75.000	GEL	✓	75	N	N		$8.5118	$8.9429	$0.6984	
45802-754-01		N	500962	Rx Gen	20.25 MG/AC		0/	0	AWP					
TESTOSTERONE 30 MG/1.5 ML P		3	ACTAVIS PH	90.000	SOLN	✓	90	N	N		$2.2539	$6.8816	$1.9873	
0591-2114-81	695338	N	500006	Rx Gen	30		0/	0	AWP					AMERISOURCE
TESTOSTERONE 40.5 MG/2.5GM		3	PERRIGO	2.500	GEL	✓	30	N	N		$11.6670	$23.0532	$12.4613	
45802-366-65	883017	N	515209	Rx Gen	40.5 MG/2.5		0/	0	AWP					AMERISOURCE
TESTOSTERONE CYP 200 MG/ML		3	HOSPIRA	1.000	SOLN	∅	~~1~~	N	N		$0.0000	$23.2900	$6.7300	
0409-6562-01	556593	N	500395	Rx Gen	200		0/	0	AWP					AMERISOURCE
TESTOSTERONE CYP 200MG/ML		3	WEST-WARD	1.000	SOLN	10	~~14~~	N	N		$0.0000	$21.6000	$12.0800	
0143-9659-01	585000	N	500395	Rx Gen	200		0/	0	AWP					AMERISOURCE
TRAMADOL 50MG TABLETS		4	AMNEAL	1000.000	TAB	✓	200	N	N		$0.0258	$0.8329	$0.0300	
65162-627-11	530941	N	502120	Rx Gen	50		0/	0	AWP					AMERISOURCE
TRIAZOLAM 0.25 MG TABS		4	HIKMA	100.000	TAB	✓	67	N	N		$1.4224	$6.0373	$1.2000	
0054-4859-25	827113	N	500374	Rx Gen	0.25		0/	0	AWP					AMERISOURCE
VIMPAT 100 MG TABLET		5	UCB PHARMA	60.000	TAB	✓	7	N	N		$0.0000	$19.5870	$15.7268	
0131-2478-60	190532	N	502680	Rx Brd	100		0/	0	AWP					AMERISOURCE
VIMPAT 150MG TABLET		5	UCB PHARMA	60.000	TAB	✓	42	N	N		$0.0000	$18.8570	$14.7683	
0131-2479-35	389534	N	502681	Rx Brd	150		0/	0	AWP					AMERISOURCE
VIMPAT 200MG TABLET		S	UCB PHARMA	60.000	TAB	✓	70	N	N		$0.0000	$18.8622	$15.1448	
0131-2480-35	389580	N	502682	Rx Brd	200		0/	0	AWP					AMERISOURCE
VIRTUSSIN AC LIQUID		5	VIRTUS PHA	473.000	SOLN	✓	411	N	N		$0.0000	$0.1010	$0.0346	
69543-252-16	490387	N	502653	OTC Brd	100-10		0/	0	AWP					AMERISOURCE
VYVANSE 20MG CAPSULE		2	SHIRE US	100.000	CAP	✓	35	N	N		$0.0000	$12.7613	$10.2463	
59417-102-10	586848	N	507924	Rx Brd	20		0/	0	AWP					AMERISOURCE
VYVANSE 30MG CAP		2	SHIRE US	100.000	CAP	✓	48	N	N		$0.0000	$12.7613	$10.2463	
59417-103-10	773566	N	507925	Rx Brd	30		0/	0	AWP					AMERISOURCE
VYVANSE 50MG CAPSULE		2	SHIRE US	100.000	CAP	✓	43	N	N		$0.0000	$12.7613	$10.2463	
59417-105-10	773578	N	508671	Rx Brd	50		0/	0	AWP					AMERISOURCE
VYVANSE 60MG CAPSULE		2	SHIRE US	100.000	CAP	✓	81	N	N		$0.0000	$12.7613	$10.2463	
59417-106-10	589806	N	512666	Rx Brd	60		0/	0	AWP					AMERISOURCE

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DRUG INVENTORY REPORT LISTING
Drug Inventory Summary by DEA Class
Wed Dec 9, 2020

PID: 5666132
NPI: 1417453226

DRUG/ NDC / PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO	QTY/RO	PT	OBS 340B PRI	MAC SCH1/PRI	AWP SCH2/PRI	AWP SCH3	COST VENDOR NAME
VYVANSE 70MG CAPSULE	2	SHIRE US	100.000	CAP	✓	75	N	N	$0.0000	$12.7613		$10.2463
59417-107-10 773585	N	507926	Rx Brd	70		0/		0 AWP				AMERISOURCE
ZALEPLON 10 MG CAPSULE	4	WEST-WARD	100.000	CAP	✓	85	N	N	$0.1590	$3.7879		$0.3683
0054-0085-25 638458	N	501021	Rx Gen	10		0/		0 AWP				AMERISOURCE
ZALEPLON 5 MG CAPS	4	RISING	100.000	CAP	✓	20	N	N	$0.1884	$3.6874		$0.1772
57237-239-01	N	501020	Rx Gen	5		0/		0 AWP				
ZALEPLON 5 MG CAPSULE	4	WEST-WARD	100.000	CAP	✓	40	N	N	$0.2391	$3.6874		$0.2731
0054-0084-25 638440	N	501020	Rx Gen	5		0/		0 AWP				AMERISOURCE
ZOLPIDEM 10MG TABLETS	4	TORRENT PH	1000.000	TAB	✓	550	N	N	$0.1139	$4.6251		$0.0249
13668-008-10 914820	N	500620	Rx Gen	10		0/		0 AWP				AMERISOURCE
ZOLPIDEM TARTRATE 5 MG TAB	4	SANDOZ	100.000	TAB	✓	50	N	N	$0.0747	$4.6254		$0.0294
0781-5317-01 771687	N	500619	Rx Gen	5		0/		0 AWP				AMERISOURCE
ZUBSOLV 2.9-0.71 MG TAB SL	3	OREXO US	30.000	TAB	✓	22	N	N	$0.0000	$10.6737		$8.5703
54123-929-30 463897	N	511944	Rx Brd	2.9-0.71		0/		0 AWP				AMERISOURCE
ZUBSOLV 5.7-1.4 MG TAB SL	3	OREXO US	30.000	TAB	✓	32	N	N	$0.0000	$10.6737		$8.5703
54123-957-30 240933	N	511945	Rx Brd	5.7-1.4		0/		0 AWP				AMERISOURCE

Biennial Control INV 12/30/22

QUALITY DRUG CLINICAL CARE
18 Technology Drive
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DRUG INVENTORY REPORT LISTING
Drug Inventory Summary Ending on 12/30/22 Incl. In-house Rx Qty For 90 Days
DEA Class: 2345

PID: 5666132
NPI: 1417453226

EOD

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO	QTY/RO	OBS PT	340B PRI SCH1/PRI SCH2/PRI SCH3	VENDOR NAME
DEXTRO-AMPHET 15MG TABLETS		2	TEVA USA	100.000	TAB	✓ 100	N	N		
0555-0777-02	1107689	N	503457	Rx Gen	15	0/	0	AWP		MCKESSON
DEXTROAMP-AMPHET 30MG TABS		2	MALLINCKRO	100.000	TAB	✓ 100	N	N		
0406-8894-01	2035830	N	503205	Rx Gen	30	0/	0	AWP		MCKESSON
DEXTROAMP-AMPHET ER 10 MG C		2	SANDOZ	100.000	CAP	✓ 285	N	N		
0781-2335-01		N	502565	Rx Gen	10	0/	0	AWP		
DEXTROAMP-AMPHET ER 25 MG C		2	SANDOZ	100.000	CAP	✓ 100	N	N		
0781-2368-01	3580180	N	502568	Rx Gen	25	0/	0	AWP		MCKESSON
DEXTROAMPH ER 5MG CAP		2	MALLINCKRO	100.000	CAP	✓ 10	N	N		
0406-8960-01	1370923	N	504162	Rx Gen	5	0/	0	AWP		MCKESSON
DIAZEPAM 10MG TAB		4	MYLAN	500.000	TAB	925 ~~927~~	N	N		
0378-0477-05	460121	N	502726	Rx Gen	10	0/	0	AWP		AMERISOURCE
DIAZEPAM 5 MG TABS		4	TEVA USA	1000.000	TAB	✓ 1000	N	N		
0172-3926-80	2112670	N	502725	Rx Gen	5	0/	0	AWP		MCKESSON
DIAZEPAM 5MG TABLET		4	MYLAN	500.000	TAB	✓ 120	N	N		
0378-0345-05	3688157	N	502725	Rx Gen	5	0/	0	AWP		MCKESSON
DIPHENOXYLATE-ATROP 2.5-0.0		5	ANI PHARMA	100.000	TAB	✓ 64	N	N		
62559-490-01	3690948	N	500653	Rx Gen	2.5-0.025	0/	0	AWP		MCKESSON
DIPHENOXYLATE-ATROPINE 2.5-		5	SPECGX	100.000	TAB	✓ 210	N	N		
0406-1236-01	1583061	N	500653	Rx Gen	2.5-0.025	0/	0	AWP		MCKESSON
ESTROGEN-METHYLTESTOS H.S.		3	ANI PHARMA	100.000	TAB	✓ 101	N	N		
62559-150-01	226969	N	506621	Rx Gen	0.625-1.25	0/	0	AWP		MCKESSON
ESZOPICLONE 1 MG TABS		4	DR.REDDY'S	30.000	TAB	✓ 90	N	N		
55111-629-30	2772093	N	501086	Rx Gen	1	0/	0	AWP		MCKESSON
ESZOPICLONE 2 MG TABLET		4	GLENMARK	100.000	TAB	✓ 115	N	N		
68462-383-01	295530	N	501087	Rx Gen	2	0/	0	AWP		MCKESSON
ESZOPICLONE 3 MG TABLET		4	DR.REDDY'S	100.000	TAB	✓ 186	N	N		
55111-617-01	2773091	N	501088	Rx Gen	3	0/	0	AWP		MCKESSON
HYDROCODON-APAP 10-325		2	AMNEAL	100.000	TAB	✓ 210	N	N		
53746-110-01	3269073	N	503128	Rx Gen	10-325	0/	0	AWP		MCKESSON
HYDROCODON-APAP 10-325		2	MALLINCKRO	100.000	TAB	✓ 400	N	N		
0406-0125-01	3284213	N	503128	Rx Gen	10-325	0/	0	AWP		MCKESSON
HYDROCODON-APAP 10-325		2	TRIS PHARM	100.000	TAB	✓ 505	N	N		
27808-037-01	3418027	N	503128	Rx Gen	10-325	0/	0	AWP		MCKESSON
HYDROCODON-APAP 5-325		2	MALLINCKRO	100.000	TAB	✓ 932	N	N		
0406-0123-01	3285020	N	503127	Rx Gen	5-325	0/	0	AWP		MCKESSON
HYDROCODON-APAP 7.5/325 TAB		2	MALLINCKRO	100.000	TAB	✓ 110	N	N		
0406-0124-01	3285038	N	504536	Rx Gen	7.5-325	0/	0	AWP		MCKESSON
HYDROCODONE BITARTRATE ER 3		2	ALVOGEN	60.000	TAB	✓ 30	N	N		
47781-393-60	1579598	N	512573	Rx Gen	30	0/	0	AWP		MCKESSON
HYDROCODONE-ACETAMINOPHEN 1		2	KVK TECH	100.000	TAB	✓ 48	N	N		
10702-191-01	3909611	N	503128	Rx Gen	10-325	0/	0	AWP		MCKESSON
HYDROCODONE-ACETAMINOPHEN 7		2	KVK TECH	100.000	TAB	✓ 20	N	N		
10702-190-01	3909603	N	504536	Rx Gen	7.5-325	0/	0	AWP		MCKESSON
HYDROMORPHONE HCL ER 12 MG		2	CAMBER PHA	100.000	TAB	✓ 85	N	N		
31722-120-01	1573419	N	525381	Rx Gen	12	0/	0	AWP		MCKESSON
HYDROMORPHONE HCL ER 8 MG T		2	CAMBER PHA	100.000	TAB	✓ 55	N	N		
31722-119-01	1573401	N	525380	Rx Gen	8	0/	0	AWP		MCKESSON

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DRUG INVENTORY REPORT LISTING
Drug Inventory Summary Ending on 12/30/22 Incl. In-house Rx Qty For 90 Days
DEA Class: 2345
Mon Apr 24, 2023

PID: 5666132
NPI: 1417453226

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO QTY	OBS/RO	PT	340B PRI	SCH1/PRI SCH2/PRI SCH3	VENDOR NAME
ACETAMINOPHEN-COD #3 TABLET		3	MALLINCKRO	100.000	TAB	11	N		N		
0406-0484-01	137450	N	502127	Rx Gen	300-30	0/		0	AWP		MCKESSON
ALPRAZOLAM 0.25 MG TABLET		4	GREENSTONE	100.000	TAB	240	N		N		
59762-3719-1	2702454	N	500379	Rx Gen	0.25	0/		0	AWP		MCKESSON
ALPRAZOLAM 0.25MG TAB		4	ACTAV PHAR	100.000	TAB	200	N		N		
0228-2027-10		N	500379	Rx Gen	0.25	0/		0	AWP		
ALPRAZOLAM 0.5 MG TABS		4	AUROBINDO	100.000	TAB	112	N		N		
65862-677-01	3503398	N	500385	Rx Gen	0.5	0/		0	AWP		MCKESSON
ALPRAZOLAM 1 MG TABLET		4	GREENSTONE	500.000	TAB	380	N		N		
59762-3721-3	2712636	N	500396	Rx Gen	1	0/		0	AWP		MCKESSON
ALPRAZOLAM 2 MG TABLET		4	GREENSTONE	100.000	TAB	177	N		N		
59762-3722-1	2712982	N	500397	Rx Gen	2	0/		0	AWP		MCKESSON
AMPHETAMINE SALTS 10MG TAB		2	TEVA USA	100.000	TAB	210	N		N		
0555-0972-02	2413953	N	503193	Rx Gen	10	0/		0	AWP		MCKESSON
AMPHETAMINE SALTS 20MG TAB		2	TEVA USA	100.000	TAB	673	N		N		
0555-0973-02	2414761	N	503204	Rx Gen	20	0/		0	AWP		MCKESSON
AMPHETAMINE SALTS 30MG TABS		2	TEVA USA	100.000	TAB	300	N		N		
0555-0974-02	2414944	N	503205	Rx Gen	30	0/		0	AWP		MCKESSON
AMPHETAMINE-DEXTROAMPHET ER		2	LANNETT	100.000	CAP	10	N		N		
0527-5510-37	1526409	N	502564	Rx Gen	5	0/		0	AWP		MCKESSON
AMPHETAMINE-DEXTROAMPHETAMI		2	LANNETT	100.000	TAB	40	N		N		
0527-1505-37	3952447	N	503204	Rx Gen	20	0/		0	AWP		MCKESSON
AMPHETAMINE-DEXTROAMPHETAMI		2	SUNRISE PH	100.000	TAB	10	N		N		
11534-192-01	1547108	N	503193	Rx Gen	10	0/		0	AWP		MCKESSON
AMPHETAMINE-DEXTROAMPHETAMI		2	RHODES PHA	100.000	TAB	20	N		N		
42858-726-01	2367845	N	503204	Rx Gen	20	0/		0	AWP		MCKESSON
ANDROGEL 1.62% GEL PUMP		3	ABBVIE	75.000	GEL	75	N		N		
0051-8462-33	1653039	N	500962	Rx Brd	20.25 MG/AC	0/		0	AWP		MCKESSON
CARISOPRODOL 350 MG TABS		4	SCIEGEN PH	100.000	TAB	113	N		N		
50228-109-01	3657822	N	500764	Rx Gen	350	0/		0	AWP		MCKESSON
CLONAZEPAM 0.5 MG TAB		4	ACCORD HEA	500.000	TAB	515	N		N		
16729-136-16	2152049	N	500144	Rx Gen	0.5	0/		0	AWP		MCKESSON
CLONAZEPAM 1 MG TAB		4	ACCORD HEA	100.000	TAB	58	N		N		
16729-137-00	2152254	N	500143	Rx Gen	1	0/		0	AWP		MCKESSON
CLONAZEPAM 1 MG TABS		4	TEVA USA	100.000	TAB	600	N		N		
0093-3212-01	3990413	N	500143	Rx Gen	1	0/		0	AWP		MCKESSON
CLONAZEPAM 2 MG TABS		4	ACCORD HEA	100.000	TAB	30	N		N		
16729-138-00	2152593	N	500146	Rx Gen	2	0/		0	AWP		MCKESSON
CLONAZEPAM 2 MG TABS		4	TEVA USA	500.000	TAB	365	N		N		
0093-3213-05	3990421	N	500146	Rx Gen	2	0/		0	AWP		MCKESSON
CLONAZEPAM 2 MG TBDP		4	SUN PHARMA	60.000	TAB	60	N		N		
57664-787-86	3699428	N	505223	Rx Gen	2	0/		0	AWP		MCKESSON
CLONAZEPAM ODT 0.25MG TAB		4	PAR PHARMA	60.000	TAB	108	N		N		
49884-307-02	1827708	N	505220	Rx Gen	0.25	0/		0	AWP		MCKESSON
D-AMPHETAMINE ER 15 MG CAP		2	MALLINCKRO	100.000	CAP	10	N		N		
0406-8962-01	1370949	N	504164	Rx Gen	15	0/		0	AWP		MCKESSON
DEPO-TESTOSTERONE 100MG/ML		3	PFIZER US	10.000	SOLN	10	N		N		
0009-0347-02	1605559	N	500394	Rx Brd	100	0/		0	AWP		MCKESSON

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Drug Inventory Summary Ending on 12/30/22 Incl. In-house Rx Qty For 90 Days
DEA Class: 2345

PID: 5666132
NPI: 1417453226

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	RO	ON-HD/ QTY/RO	OBS PT	340B PRI SCH1/PRI SCH2/PRI SCH3	VENDOR NAME
HYSINGLA ER 40 MG T24A		2	PURDUE	60.000	TAB	✓	30	N	N	
59011-273-60	3407400	N	512574	Rx Brd	40		0/	0	AWP	MCKESSON
KETALAR 50 MG/ML SOLN		3	PAR STERIL	10.000	SOLN	✓	30	N	N	
42023-114-10	1383405	N	502774	Rx Brd	50		0/	0	AWP	MCKESSON
LACOSAMIDE 100 MG TABS		5	BRENCKRDG	60.000	TAB	✓	60	N	N	
51991-349-06	1504398	N	502680	Rx Gen	100		0/	0	AWP	MCKESSON
LORAZEPAM 0.5 MG TABS		4	TEVA USA	500.000	TAB	✓	106	N	N	
0093-3425-05	733836	N	502299	Rx Gen	0.5		0/	0	AWP	AMERISOURCE
LORAZEPAM 1 MG TABS		4	TEVA USA	1000.000	TAB	946	846	N	N	
0093-3426-10	2381952	N	502300	Rx Gen	1		0/	0	AWP	MCKESSON
LORAZEPAM 2 MG TABS		4	TEVA USA	100.000	TAB	✓	181	N	N	
0093-3427-01	2343812	N	502301	Rx Gen	2		0/	0	AWP	MCKESSON
METHADONE 10MG TAB		2	MALLINCKRO	100.000	TAB	✓	80	N	N	
0406-5771-01	1953405	N	501176	Rx Gen	10		0/	0	AWP	MCKESSON
METHYLPHENIDATE HCL 10 MG T		2	KVK TECH	100.000	TAB	✓	180	N	N	
10702-101-01	3672938	N	501842	Rx Gen	10		0/	0	AWP	MCKESSON
METHYLPHENIDATE HCL ER 27 M		2	TRIGEN LAB	100.000	TAB	✓	10	N	N	
13811-707-10	3711728	N	504354	Rx Gen	27		0/	0	AWP	MCKESSON
MORPHINE SULF ER 15MG TABS		2	MALLINCKRO	100.000	TAB	✓	105	N	N	
0406-8315-01	2474641	N	503471	Rx Gen	15		0/	0	AWP	MCKESSON
OXYCODONE 30MG TABLET		2	KVK TECH	100.000	TAB	✓	200	N	N	
10702-009-01	1495415	N	503450	Rx Gen	30		0/	0	AWP	MCKESSON
OXYCODONE HCL 10 MG TABS		2	AMNEAL	100.000	TAB	✓	80	N	N	
65162-048-10	3426343	N	505436	Rx Gen	10		0/	0	AWP	MCKESSON
OXYCODONE HCL 15 MG TABLET		2	KVK TECH	100.000	TAB	✓	73	N	N	
10702-008-01	1495324	N	503449	Rx Gen	15		0/	0	AWP	MCKESSON
OXYCODONE HCL 20 MG TABS		2	RHODES PHA	100.000	TAB	✓	300	N	N	
42858-004-01	3245529	N	505437	Rx Gen	20		0/	0	AWP	MCKESSON
OXYCODONE HCL 30 MG TABS		2	RHODES PHA	100.000	TAB	✓	445	N	N	
42858-005-01	3245578	N	503450	Rx Gen	30		0/	0	AWP	MCKESSON
OXYCODONE-APAP 10/325MG TAB		2	RHODES PHA	100.000	TAB	✓	280	N	N	
42858-104-01	3295177	N	503454	Rx Gen	10-325		0/	0	AWP	MCKESSON
OXYCODONE-APAP 5-325MG TABS		2	RHODES PHA	100.000	TAB	✓	306	N	N	
42858-102-01	3295193	N	501130	Rx Gen	5-325		0/	0	AWP	MCKESSON
OXYCODONE/APAP 5/325MG TAB		2	MALLINCKRO	100.000	TAB	✓	88	N	N	
0406-0512-01	3285335	N	501130	Rx Gen	5-325		0/	0	AWP	MCKESSON
OXYCONTIN 80MG		2	PURDUE	100.000	TAB	✓	306	N	N	
59011-480-10	2136760	N	502357	Rx Brd	80		0/	0	AWP	MCKESSON
PHENOBARBITAL 64.8 MG TABS		4	ECI PHARMA	1000.000	TAB	✓	417	N	N	
51293-627-10	3910718	N	505442	Rx Gen	64.8		0/	0	AWP	MCKESSON
PREGABALIN 150 MG CAPS		5	CIPLA USA	90.000	CAP	✓	122	N	N	
69097-682-05	1564707	N	501608	Rx Gen	150		0/	0	AWP	MCKESSON
PREGABALIN 50 MG CAPS		5	CIPLA USA	90.000	CAP	✓	180	N	N	
69097-678-05	1564673	N	501605	Rx Gen	50		0/	0	DEFAULT	MCKESSON
PREGABALIN 50 MG CAPS		5	SUN PHARMA	100.000	CAP	✓	20	N	N	
47335-687-88	2312254	N	501605	Rx Gen	50		0/	0	AWP	MCKESSON
PREGABALIN 75 MG CAPS		5	CIPLA USA	90.000	CAP	✓	30	N	N	
69097-679-05	1564681	N	501605	Rx Gen	75		0/	0	DEFAULT	MCKESSON

QUALITY DRUG CLINICAL CARE
18 Technology Drive
Suite 104
Irvine, CA 92618
(949) 471-0223

DRUG INVENTORY REPORT LISTING
Drug Inventory Summary Ending on 12/30/22 Incl. In-house Rx Qty For 90 Days
DEA Class: 2345

PID: 5666132
NPI: 1417453226

DRUG/ NDC PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RO QTY/RO	OBS PT	340B PRI SCH1/PRI SCH2/PRI SCH3	VENDOR NAME
TEMAZEPAM 15 MG CAPSULE	4	ASCENDLABS	100.000	CAP	✓ 38	N	N	
67877-146-01 1723899	N	503430	Rx Gen	15	0/	0	AWP	MCKESSON
TEMAZEPAM 30 MG CAPS	4	ASCENDLABS	100.000	CAP	✓ 50	N	N	
67877-147-01 1723923	N	503431	Rx Gen	30	0/	0	AWP	MCKESSON
TESTOST CYP 2,000 MG/10ML*	3	WEST-WARD	10.000	SOLN	✓ 30	N	N	
0143-9726-01	N	500395	Rx Gen	200	0/	0	AWP	
TESTOSTERONE 1.62 % GEL	3	AMNEAL	75.000	GEL	✓ 1125	N	N	
69238-1013-2 886143	N	500962	Rx Gen	1.62	0/	0	AWP	MCKESSON
TESTOSTERONE 1.62 % GEL	3	XIROMED	75.000	GEL	✓ 75	N	N	
70700-112-21 1558246	N	500962	Rx Gen	1.62	0/	0	AWP	MCKESSON
TESTOSTERONE 1.62 % GEL	3	NORTHSTAR	75.000	GEL	✓ 375	N	N	
16714-967-01 3952157	N	500962	Rx Gen	1.62	0/	0	AWP	MCKESSON
TESTOSTERONE 12.5 MG/1.25 G	3	ACTAVIS PH	75.000	GEL	✓ 450	N	N	
0591-2921-02 504589	N	500963	Rx Gen	12.5 MG/ACT	0/	0	AWP	AMERISOURCE
TESTOSTERONE 20.25 MG/ACT (	3	LUPIN PHRM	75.000	GEL	✓ 1125	N	N	
68180-941-11 3943743	N	500962	Rx Gen	20.25 MG/AC	0/	0	AWP	MCKESSON
TESTOSTERONE 25 MG/2.5GM (1	3	STRIDES PH	2.500	GEL	✓ 90	N	N	
64380-151-02 2635068	N	515207	Rx Gen	25 MG/2.5GM	0/	0	AWP	MCKESSON
TESTOSTERONE 40.5 MG/2.5GM	3	PADAGIS	2.500	GEL	✓ 150	N	N	
45802-366-65 3962537	N	515209	Rx Gen	40.5 MG/2.5	0/	0	AWP	MCKESSON
TESTOSTERONE 50 MG/5GM (1%)	3	ENCUBE ETH	5.000	GEL	✓ 300	N	N	
21922-019-02 2397073	N	515208	Rx Gen	50 MG/5GM	0/	0	AWP	MCKESSON
TESTOSTERONE CYP 200 MG/ML	3	HOSPIRA	10.000	SOLN	✓ 20	N	N	
0409-6562-20 556597	N	500395	Rx Gen	200	0/	0	AWP	MCKESSON
TESTOSTERONE CYP 200MG/ML	3	WEST-WARD	1.000	SOLN	14 ~~200~~	N	N	
0143-9659-01 3602687	N	500395	Rx Gen	200	0/	0	AWP	MCKESSON
TESTOSTERONE CYPIONATE 200	3	PERRIGO	1.000	SOLN	✓ 10	N	N	
0574-0827-01 2318566	N	500395	Rx Gen	200	0/	0	AWP	MCKESSON
TRAMADOL 50MG TABLET	4	AMNEAL	500.000	TAB	✓ 370	N	N	
65162-627-50 3209400	N	502120	Rx Gen	50	0/	0	AWP	MCKESSON
VIMPAT 200MG TABLET	5	UCB PHARMA	60.000	TAB	✓ 53	N	N	
0131-2480-35 2427342	N	502682	Rx Brd	200	0/	0	AWP	MCKESSON
VYVANSE 20MG CAPSULE	2	SHIRE US	100.000	CAP	✓ 60	N	N	
59417-102-10 1480318	N	507924	Rx Brd	20	0/	0	AWP	MCKESSON
VYVANSE 30MG CAP	2	SHIRE US	100.000	CAP	✓ 88	N	N	
59417-103-10 1764430	N	507925	Rx Brd	30	0/	0	AWP	MCKESSON
VYVANSE 40MG CAPSULE	2	SHIRE US	100.000	CAP	✓ 80	N	N	
59417-104-10 1481258	N	512135	Rx Brd	40	0/	0	AWP	MCKESSON
VYVANSE 50MG CAPSULE	2	SHIRE US	100.000	CAP	✓ 192	N	N	
59417-105-10 1770502	N	508671	Rx Brd	50	0/	0	AWP	MCKESSON
VYVANSE 60MG CAPSULE	2	SHIRE US	100.000	CAP	✓ 71	N	N	
59417-106-10 1482389	N	512666	Rx Brd	60	0/	0	AWP	MCKESSON
ZALEPLON 10 MG CAPS	4	RISING	100.000	CAP	✓ 170	N	N	
57237-240-01 738807	N	501021	Rx Gen	10	0/	0	AWP	MCKESSON
ZALEPLON 10 MG CAPS	4	AUROBINDO	100.000	CAP	✓ 60	N	N	
65862-215-01 1718865	N	501021	Rx Gen	10	0/	0	AWP	MCKESSON
ZALEPLON 10 MG CAPSULE	4	UNICHEM	100.000	CAP	✓ 20	N	N	
29300-132-01 1985282	N	501021	Rx Gen	10	0/	0	AWP	MCKESSON

QUALITY DRUG CLINICAL CARE
18 Technology Drive
Suite 104
Irvine, CA 92618
(949) 471-0223

DRUG INVENTORY REPORT LISTING
Drug Inventory Summary Ending on 12/30/22 Incl. In-house Rx Qty For 90 Days
DEA Class: 2345

PID: 5666132
NPI: 1417453226

DRUG/ NDC	PROD. CODE	DEA/ TAX	LABELER/ GENERIC	PACKAGE/ TYPE	FORM/ STRENGTH	ON-HD/ RQ	QTY/RQ	OBS PT	340B PRI	SCH1/PRI	SCH2/PRI	SCH3	VENDOR NAME
ZALEPLON 5 MG CAPSULE		4	WEST-WARD	100.000	CAP		140	N	N				
0054-0084-25	1764489	N	501020	Rx Gen	5		0/	0	AWP				MCKESSON
ZOLPIDEM 10MG TAB		4	TEVA USA	100.000	TAB		10	N	N				
0093-0074-01	1624360	N	500620	Rx Gen	10		0/	0	AWP				MCKESSON
ZOLPIDEM 10MG TABLETS		4	TORRENT PH	1000.000	TAB		470	N	N				
11668-008-10	3601325	N	500620	Rx Gen	10		0/	0	AWP				MCKESSON
ZOLPIDEM 5MG TAB		4	NORTHSTAR	100.000	TAB		70	N	N				
16714-621-01	3281284	N	500619	Rx Gen	5		0/	0	AWP				MCKESSON
ZOLPIDEM TARTRATE 3.5 MG SU		4	PAR PHARMA	30.000	TAB		30	N	N				
49884-899-11	3403912	N	509715	Rx Gen	3.5		0/	0	AWP				MCKESSON

1:5 470/656

QUALITY DRUG CLINICAL CARE
18 TECHNOLOGY DR STE 104
IRVINE, CA 92618-5303

10008475.2/002442-1/1-0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FQ7438965	04-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

QUALITY DRUG CLINICAL CARE
18 TECHNOLOGY DR STE 104
IRVINE, CA 92618-5303

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FQ7438965	04-30-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

QUALITY DRUG CLINICAL CARE
18 TECHNOLOGY DR STE 104
IRVINE, CA 92618-5303

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Form DEA-223 (9/2016)

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	QUALITY DRUG CORPORATION
Entity No.:	1917976
Registration Date:	12/09/1994
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of November 27, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 161406521

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

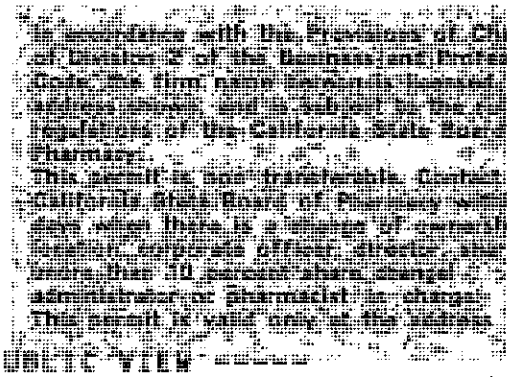
CALIFORNIA STATE BOARD OF PHARMA
2720 GATEWAY OAKS DRIVE, SUITE 1
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 58254
RECEIPT NO. 31310363

VALID UNTIL JULY 01, 2024



QUALITY DRUG CLINICAL CARE
18 TECHNOLOGY DR STE 104
IRVINE CA 92618

05/15/23
05/15/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (0

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 5, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: QUALITY DRUG CLINICAL CARE

License Type: PHARMACY

License Number: PHY 58254

Status: ACTIVE

Issue Date: 07/01/2021

Expiration Date: 07/01/2024

Address of Record: 18 TECHNOLOGY DR STE 104 IRVINE, CA 92618

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Quality Drug Corporation

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 18 Technology Drive, Suite 104

City: Irvine State: CA Zip: 92618-5303

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 833-210-5968 Website: www.lumicera.com

Licensing Company Email: licensing@lumicera.com

Section 2: Personal Information

First: Sebastian Middle: Jan Last: Zapart

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]Cheshire

City: Mission Viejo State: CA Zip: 92618

Telephone: [redacted] Email: Sebastian.Zapart@lumicera.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Pharmacy & Science		9/99 - 5/03	
Address	City	State	Zip
600 S 43rd St	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Pharm D			

School Name		From - To (MM/YY – MM/YY)	
Temple University		9/96 - 6/98	
Address	City	State	Zip
1801 N Broad St	Philadelphia	PA	19122
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Bodine High School for International Affairs		9/92 - 6/96	
Address	City	State	Zip
1101 N 4th St.	Philadelphia	PA	19123
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]Cheshire	Mission Viejo	CA	92692
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.593S) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Quality Drug Corporation			7/1/23 – present
Business Address	**City**	**State**	**Zip**
18 Technology Drive Suite 104	Irvine	CA	92618-5303
Phone	**Title**	**Number of Employed Hours**	
833-210-5968	Pharmacist-in-Charge, Specialty Pharmacy		
Description of Duties			
Filling, Dispensing, Inventory, ordering & all duties of a pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Quality Drug Corporation			2/2010 - 6/2021
Business Address	**City**	**State**	**Zip**
239 Broadway	Laguna Beach	CA	92651
Phone	**Title**	**Number of Employed Hours**	
949-471-0223	Pharmacist in charge	25,000	
Description of Duties			
Same as above			

Business Name			From - To (MM/YY – MM/YY)
CVS			6/2007 - 1/2010
Business Address	**City**	**State**	**Zip**
25272 Marguerite Pkwy	Mission Viejo	CA	92692
Phone	**Title**	**Number of Employed Hours**	
949-455-9539	Pharmacist in charge	5,200	
Description of Duties			
Same as above			

Business Name			From - To (MM/YY – MM/YY)
Eckerd Drug			6/03 - 3/07
Business Address	**City**	**State**	**Zip**
2545 Aramingo Ave	Philadelphia	PA	19134
Phone	**Title**	**Number of Employed Hours**	
215 - 743 - 8530	Pharmacist in Charge	7500	
Description of Duties			
Same as above			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Sebastian Zapart, **certify that as the designated representative for**

Quality Drug Corporation,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SZ I am at least 21 years of age;
3. SZ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SZ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SZ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SZ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SZ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sebastian Zapart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/11/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sebastian Zapart
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/11/24
Date

Please have this section completed in the presence of a Notary Public.

State of CALIF, ss. County of ORANGE

I, FRANK MATSUMOTO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-11-24
Date

Subscribed and Sworn to before me this 11 day of JAN

Notary Public Signature

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sebastian Zapart

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/11/24

Date

Please have this section completed in the presence of a Notary Public.

State of CALIF, ss. County of ORANGE

I, FRANK MATSUMOTO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-11-24

Date

Subscribed and Sworn to before me this 11 day of JAN.

Notary Public Signature

FRANK MATSUMOTO
Notary Public - California
Orange County
Commission # 2434830
My Comm. Expires Jan. 15, 2027

(Seal)

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, NV 89521

APPLICATION FOR NEVADA WAREHOUSE LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **non-transferable checks only**)

Application must be printed legibly or typed

* FEE PAID FOR MDEG LICENSE

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New Warehouse ☐ Ownership Change ☐ Name Change ☐ Location Change
(Please provide current license number if making changes: WA _____)

☐ Publicly Traded Corporation – Page 1,2,3,4 ☐ Partnership - Page 1,2,3,6,6a
☑ Non Publicly Traded Corporation – Page 1,2,3,5,5a,5b ☐ Sole Owner – Page 1,2,3,7,7a
Please check box for type of ownership and complete correct part of the application.

GENERAL INFORMATION

Facility Name: PACIFIC MEDICAL, INC.

Physical Address: 123 W. NYE LANE

Mailing Address: SAME

City: CARSON CITY State: NV Zip Code: 89706

Telephone: 775 324-2394 Fax: 775 324-2918

Toll Free Number: 800 726-9180

E-mail: jwadhams@pacmedical.com Website: www.PACMEDICAL.com

Facility Manager: JEN WADHAMS

Professional qualifications and experience of facility manager: _____

Types of licensed outlets or authorized persons firm will serve:

☐ Pharmacies ☐ Manufacturer ☐ Chain Warehouse ☐ Wholesalers
☑ Other: DMEPOS Distributors

Type of Products to be handled or wholesaled be firm:

☐ Legend Pharmaceuticals, Supplies or Devices ☐ Hypodermic Devices
☐ Poisons or Chemicals ☐ Veterinary Legend Drugs
☐ Controlled Substances (include copy of DEA)
☒ Other: DMEPOS (Bracing and rehab ~~orthotic~~ products)

APPLICATION FOR NEVADA WAREHOUSE LICENSE

Do any shareholders hold an interest ownership or have management in any type of business or facility which are licensed by the State of Nevada or another political jurisdiction? Yes ☐ No ☑

List the top 4 suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

1) Top Shelf Manufacturing, LLC 1851 E. Paradise Rd, #B Tracy CA 95304
Name Address Business

2) DJD, LLC 2900 Lake Vista Dr. #200, Lewisville, TX 75067
Name Address Business

3) Bees, Inc 2382 Faraday Ave, #300, Carlsbad, CA 92008
Name Address Business

4) Medline 1 Three Lakes Dr, Northfield, IL 60093
Name Address Business

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been the subject of an administrative action or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

APPLICATION FOR NEVADA WAREHOUSE LICENSE

This page must be submitted for all types of ownership.

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest) or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized warehouse may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

Mark Weaver
Print Name of Authorized Person

1.3.2024
Date

Board Use Only	Received: 1/8/24	Amount:

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A PUBLICLY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City:_____ State:_____ Zip: _____

Telephone:_____ Fax:_____

Contact Person: _____

Ownership Information – Complete Section 1 or 2

Do not use N/A in this section – Section 1 or 2 must be completed.

Section 1: List the corporations four largest shareholders:
(Name and percentage of ownership)

1._____ %: _____

2._____ %: _____

3._____ %: _____

4._____ %: _____

Section 2: If the corporation that holds an ownership interest in the applicant is a publicly traded corporation, the applicant shall identify the officers of that corporation, the date the corporation received its registration with the SEC, the registration number issued and the exchange at which the stock is being traded. You can provide a copy of the SEC report or copy of Form 10-K.

*Date of Incorporation: _____

*Registration number issued: _____

*Stock Exchange: _____

Include with the application for a publicly traded corporation

List of officers and directors.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A NON-PUBLICY TRADED CORPORATION

State of Incorporation: _____

Parent Company if any: _____

Corporation Name: _____

Mailing Address: _____

City:_____State:_____Zip:_____

Telephone:_____Fax:_____

Contact Person: _____

For any corporation non publicly traded, disclose the following:

1) List any persons to whom the shares were issued by the corporation?

a)_____
Name Address

b)_____
Name Address

c)_____
Name Address

d)_____
Name Address

NOTE: All persons who are stockholders must accurately complete a personal history record form. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses.*

2) Provide the number of shares issued by the corporation. _____

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

Application for Nevada Warehouse License

Include with the application for a non-publicly traded corporation

List of officers and directors.

Certificate of Corporate status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A PARTNERSHIP.

List names of 4 largest partners and percentage of ownership:

Name:_____%:_____

Name:_____%:_____

Name:_____%:_____

Name:_____%: _____

Partnership Name: _____

Mailing Address: _____

City:_____State:_____Zip:_____

Telephone:_____Fax:_____

Contact Person: _____

Include with the application for a partnership

Complete personal history record for each stockholder. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*. Must be original signature(s), no copies or stamp.

APPLICATION FOR NEVADA WAREHOUSE LICENSE

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name: _____

Business Name: _____

Current Business Address: _____

City:_____State:_____Zip: _____

Telephone:_____ Fax: _____

Include with the application for a sole owner

Complete personal history record . Must be original signature(s), no copies or stamps. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*.

OREGON BOARD OF PHARMACY

Confirmation

You must select the "Continue" button below to complete your transaction.

Please keep a record of your Confirmation Number, or print this page for your records.

Confirmation Number **PHRMCY000192359**

Payment Details

Description OR BD PHARMACY
Licensing Board Fees
www.oregon.gov/pharmacy

Payment Amount $75.00

Payment Date 01/03/2024

Status PROCESSED

License Number NPC-0003537

Payment ID Number 247974

Licensee Name PACIFIC MEDICAL INC

Item Summary Renewal Fee $75.00; Delinquent Fee $0.00

Payment Method

Payer Name Jeffrey Leonard

Card Number *3000

Card Type American Express

Approval Code 293714

Confirmation Email jleonard@pacmedical.com

Billing Address

Address 1 1700 N Chrisman Rd

City Tracy

State CA

Zip Code 95304

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	ASC04251	☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Advanced Orthopaedic Surgery Center, LLC d/b/a Las Vegas Institute for Advanced Surgery

Physical Address: 7183 Advanced Way

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 936-7657 Fax: _____

Contact Email: sepbady@yahoo.com Website _____

Nevada Business License # NV20011113069

Employed/Contracted Pharmacist Name: Mary Grear NV Pharmacist License #: 10687

Medical Director Name: Sep Bady, M.D.

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Advanced Orthopaedic Surgery Center, LLC

Mailing Address: 7195 Advanced Way

City: Las Vegas State: NV Zip: 89113

Telephone: (702) 936-7657 Email: sepbady@yahoo.com

Contact Person Name: Sep Bady, M.D.

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ■ Yes ☐ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Mary Grear NV Pharmacist License #: 10687

As the employed/contracted pharmacist, for (ASC/RC Name): Advanced Orthopaedic Surgery Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/24/2002	May 2002	NV	Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
02-036-RPH-S	NV State Board of Pharmacy

Reason/Charge
Complaint concerning records of PRN, Inc.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Mary Grear	

Name of Business/Industry/Entity
PRN, Inc.

Provide explanation below:

A complaint was made concerning grants made by the Board of Pharmacy to PRN, Inc. to Mary Grear, Executive Director. The Board of Pharmacy sent notice of a request for hearing to the wrong mailing address even though the correct address was on file at the Board Office. This resulted in my not being aware that I needed to appear until after the Board Meeting. I subsequently prepared the requested documents and submitted them to the Board Auditors who found no discrepancies in the funds granted by the Board of Pharmacy to PRN and the expense record under my administration. A rehearing was held and the case was closed finding all monies were accounted for the PRN, Inc. grants.

Mary Grear, RPh — 1/21/24

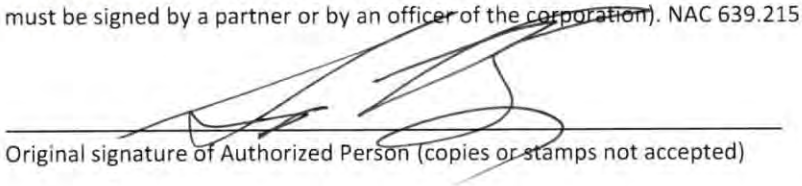
Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted) — Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sep Bady, M.D.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

1/8/24

Date

Board Use Only	Date Received: 1/24/24	Amount: $500-cc

Advanced Orthopaedic Surgery Center, LLC

Board Members (post-Closing):

- Claude Wise
- Karla Perez
- Sep Bady, M.D.
- X. Nick Liu, D.O.
- Timothy Trainor, M.D.
- Michael Trainor, D.O.

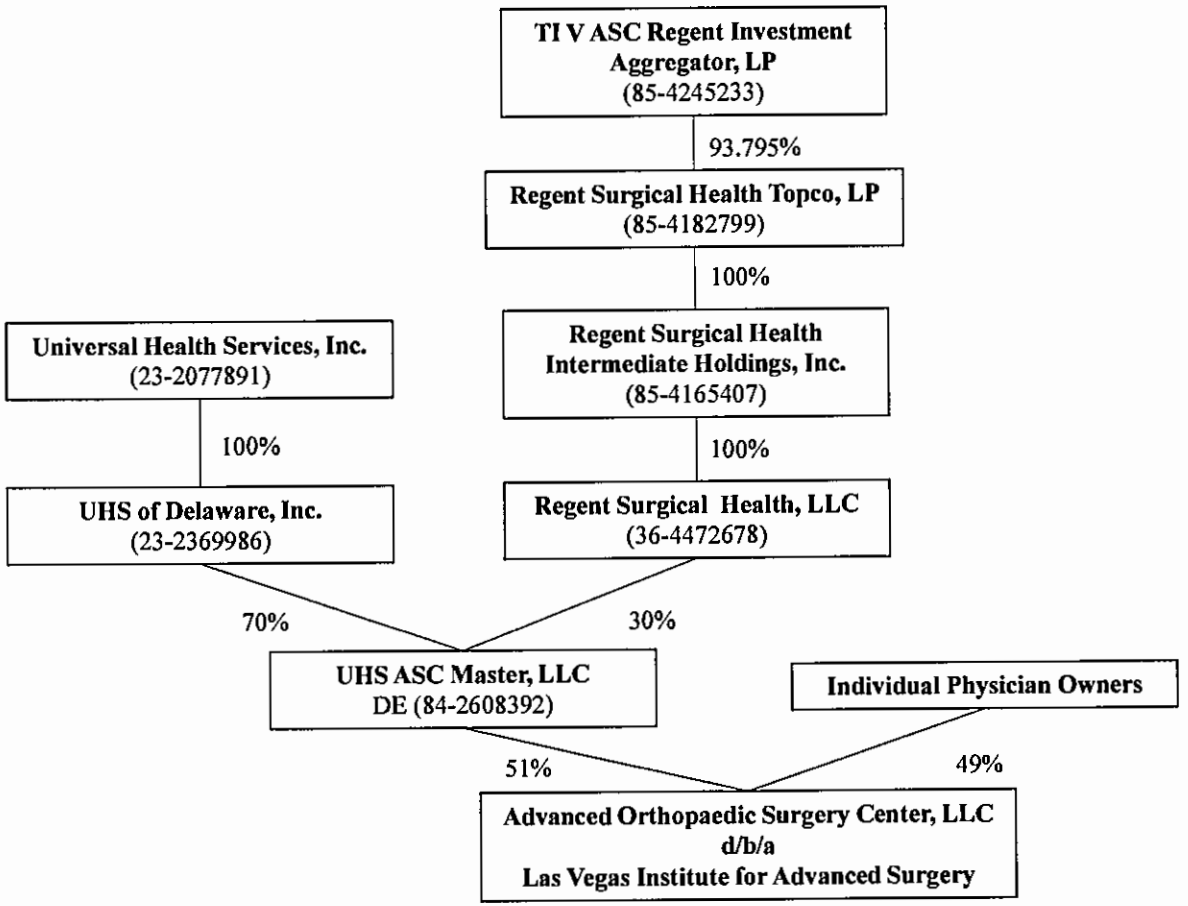
Top 4 Stockholders (post-Closing):

UHS of Delaware, Inc.	51.00%
X. Nick Liu, D.O.	12.054%
Trainor Family Trust dated May 18, 2012 (Timothy Trainor, MD)	12.054%
Thomman Kuruvilla, DPM	7.971%
Sep Bady, M.D.	7.971%
Trainor Family Living Trust dated May 18, 2012 (Michael Trainor, MD)	7.971%
Gary Morris, MD	0.980%

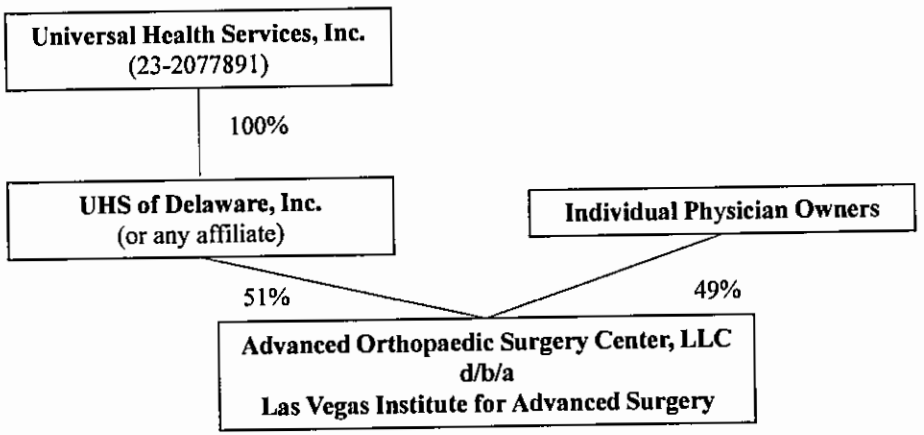
All Stockholders holding 10% or more ownership (post-Closing):

- UHS of Delaware, Inc.
- X. Nick Liu, D.O.
- Trainor Family Trust dated May 18, 2012 (Timothy Trainor, MD)

Ownership Structure of Advanced Orthopaedic Surgery Center, LLC d/b/a Las Vegas Institute for Advanced Surgery



Post-Closing Ownership Structure of Advanced Orthopaedic Surgery Center, LLC d/b/a Las Vegas Institute for Advanced Surgery



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **ADVANCED ORTHOPAEDIC SURGERY CENTER, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/25/2018, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/18/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202401184274961
You may verify this certificate online at http://www.nvsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Las Vegas Institute for Advanced Surgery

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) ASC04251

Physical Address 7183 Advanced Way

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Timothy Middle James Last Trainor

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Advanced Way

City Las Vegas State NV Zip 89113

Telephone [redacted] Email _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Notre Dame		09/88 - 05/1992	
Address	**City**	**State**	**Zip**
University of Notre Dame	Notre Dame	IN	46556
Diploma/Degree obtained, if any			
B. A.			

School Name		From - To (MM/YY – MM/YY)	
Northwestern University Medical School		08/93 - 06/97	
Address	**City**	**State**	**Zip**
303 East Chicago Ave	Chicago	IL	60611
Diploma/Degree obtained, if any			
MD			

School Name		From - To (MM/YY – MM/YY)	
Fitchburg High School			
Address	**City**	**State**	**Zip**
140 ArnHow Farm Road	Fitchburg	MA	01420
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/17 - Present	[redacted]Quiet Moon Lane	Las Vegas	NV	89135
04/09 - 05/17	[redacted]Queen Charlotte Dr.	Las Vegas	NV	89145

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Orthopaedics & Sports Medicine			07/2007 - Present	
Business Address	**City**		**State**	**Zip**
7195 Advanced Way	Las Vegas		NV	89113
Phone	**Title**			
702-740-5327	Provider/Partner			
Description of Duties				
Medical Staff/Surgeon				

Business Name			From - To (MM/YY – MM/YY)	
Las Vegas Institute for Advanced Surgery			03/20 - Present	
Business Address	**City**		**State**	**Zip**
7183 Advanced Way	Las Vegas		NV	89113
Phone	**Title**			
702-936-7657	Member			
Description of Duties				
Member/Surgeon				

Business Name			From - To (MM/YY – MM/YY)	
Durango Outpatient Surgery Center			Termed 2018	
Business Address	**City**		**State**	**Zip**
8530 W Sunset Rd	Las Vegas		NV	89113
Phone	**Title**			
702-789-5700	Surgeon/Partner			
Description of Duties				
Surgeon				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Timothy Trainor

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/18/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, TIMOTHY TRAINOR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, ~~registration,~~ permit, certificate or certification for which I am applying for.

Original Signature

1/18/24

Date

Subscribed and Sworn to before me this 18 day of January 2024

Notary Public Signature

CARLOS CALDERON
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-5417-01
MY APPT. EXPIRES JUNE 11, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Las Vegas Institute for Advanced Surgery

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) ASC04251

Physical Address 7183 Advanced Way

City Las Vegas State NV Zip 89113

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Xin Middle Nick Last Liu

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted] Advanced Way

City Las Vegas State NV Zip 89113

Telephone [redacted] Email _____

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California At Davis		09/1990 -12/1993	
Address	**City**	**State**	**Zip**
178 Mrak Hall Dr.	Davis	CA	95616
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Western University Osteopathic Medicine of the Pacific		06/1995 - 06/1999	
Address	**City**	**State**	**Zip**
309 E 2nd St. College Plaza	Pomona	CA	91766
Diploma/Degree obtained, if any			
D.O.			

School Name		From - To (MM/YY – MM/YY)	
Alhambra High School		9/1986 - 06/1990	
Address	**City**	**State**	**Zip**
150 E Street	Martinez	CA	94553
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2000 - 06/2004	[redacted]Harrington Blvd.	Mount Clemens	MI	48043
01/2002 - 03/2002	[redacted]Winslow Ave., Suite 107	Avondale	OH	45206
2012 - Current	[redacted] Saint Croix St.	Henderson	NV	89012

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Advanced Orthopaedics & Sports Medicine			08/2007 - Present	
Business Address	**City**		**State**	**Zip**
7195 Advanced Way	Las Vegas		NV	89113
Phone	**Title**			
702-740-5327	Provider/Partner			
Description of Duties				
Medical Staff				

Business Name			From - To (MM/YY – MM/YY)	
8428 Warm Springs, LLC			2018 - 2022	
Business Address	**City**		**State**	**Zip**
7189 Advanced Way	Las Vegas		NV	89113
Phone	**Title**			
702-740-5327	Member			
Description of Duties				
Landlord				

Business Name			From - To (MM/YY – MM/YY)	
Vegas Ortho LLC			2018 -2022	
Business Address	**City**		**State**	**Zip**
7195 Advanced Way	Las Vegas		NV	89113
Phone	**Title**			
702-740-5327	Member			
Description of Duties				
Landlord				

Business Name			From - To (MM/YY – MM/YY)	
Hi Five LLC			2017 - 2022	
Business Address	**City**		**State**	**Zip**
2904 W Horizon Ridge Pkwy.	Henderson		NV	89052
Phone	**Title**			
702-740-5327	Member			
Description of Duties				
Landlord				

Business Name			From - To (MM/YY – MM/YY)	
Five Star Sitters LLC				
Business Address	**City**		**State**	**Zip**
7322 S Rainbow Blvd., Suite 307	Las Vegas		NV	89139
Phone	**Title**			
702-740-5327	Member			
Description of Duties				
Nanny Service				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Parkway Surgery Center			Current	
Business Address		City	State	Zip
100 N Green Valley Pkwy. #125		Henderson	NV	89074
Phone	Title			
702-740-5327	Shareholder			
Description of Duties				
ASC				

Business Name			From - To (MM/YY – MM/YY)	
Durango Outpatient Surgery Center			Term - 2018	
Business Address		City	State	Zip
8530 W Sunset Rd.		Las Vegas	NV	89113
Phone	Title			
702-740-5327	Shareholder			
Description of Duties				
ASC				

Business Name			From - To (MM/YY – MM/YY)	
Jing Restaurant			2020 - Current	
Business Address		City	State	Zip
10975 Oval Park Dr.		Las Vegas	NV	89135
Phone	Title			
702-333-1512	Shareholder			
Description of Duties				
Restaurant				

Business Name			From - To (MM/YY – MM/YY)	
Trufusion/Truhealth Holdings			Current	
Business Address		City	State	Zip
1870 Festival Plaza, #200		Las Vegas	NV	89135
Phone	Title			
702-906-2777	Shareholder			
Description of Duties				
Gym				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Xin Nick Liu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/18/24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Xin Nick Liu, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/18/24

Date

Subscribed and Sworn to before me this 18 day of January 2024

Notary Public Signature

CARLOS CALDERON
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-5417-01
MY APPT. EXPIRES JUNE 11, 2024

(Seal)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA9696292	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	HOSPITAL/CLINIC	06-12-2023

ADVANCED ORTHOPAEDIC SURGERY CENTER, LLC
DBA LAS VEGAS INSTITUTE FOR ADVANCED SURGERY
7183 ADVANCED WAY
LAS VEGAS, NV 89113

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA9696292	06-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	HOSPITAL/CLINIC	06-12-2023

ADVANCED ORTHOPAEDIC SURGERY CENTER, LLC
DBA LAS VEGAS INSTITUTE FOR ADVANCED SURGERY
7183 ADVANCED WAY
LAS VEGAS, NV 89113

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility		
☑ Ambulatory Surgical Center (ASC)		
☐ Recovery Center (RC)		
Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☑ Ownership Change*	ASC03234	☑ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Nevada Surgical Suites

Physical Address: 2809 W Charleston Boulevard, Suite 100

City: Las Vegas State: Nevada Zip: 89102

Mailing Address (if different from physical address): See physical address

City: _____ State: _____ Zip: _____

Telephone: 702-743-8986 Fax: (702) 476-9500

Contact Email: julie.woodward@nvcpc.com Website https://nevadasurgicalsuites.com/location/

Nevada Business License # NV20121456024

Employed/Contracted Pharmacist Name: Todd Bleak NV Pharmacist License #: 11505

Medical Director Name: Alain Coppel

Days of Operation

☑ Monday	☑ Tuesday	☑ Wednesday	☑ Thursday	☑ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Surgery Center Holdings, Inc.

Corporation/Organization Name: Coppel Surgical Solutions, LLC

Mailing Address: 2809 W Charleston Boulevard, Suite 100

City: Las Vegas State: Nevada Zip: 89102

Telephone: 702-743-8986 Email: julie.woodward@nvcpc.com

Contact Person Name: Julie Woodward, Administrator

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Todd Bleak, PharmD NV Pharmacist License #: 11505

As the employed/contracted pharmacist, for (ASC/RC Name): Nevada Surgical Suites :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

11-03-2023

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jennifer Baldock, Vice President and Secretary of Administrative Member, Surgery Center Holdings, Inc.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Jennifer Baldock

Original signature of Authorized Person (copies or stamps not accepted)

November 3, 2023

Date

Board Use Only	Date Received: 11/13/23	Amount: $500 check 28781

Exhibit to Section 9: Ownership & Management

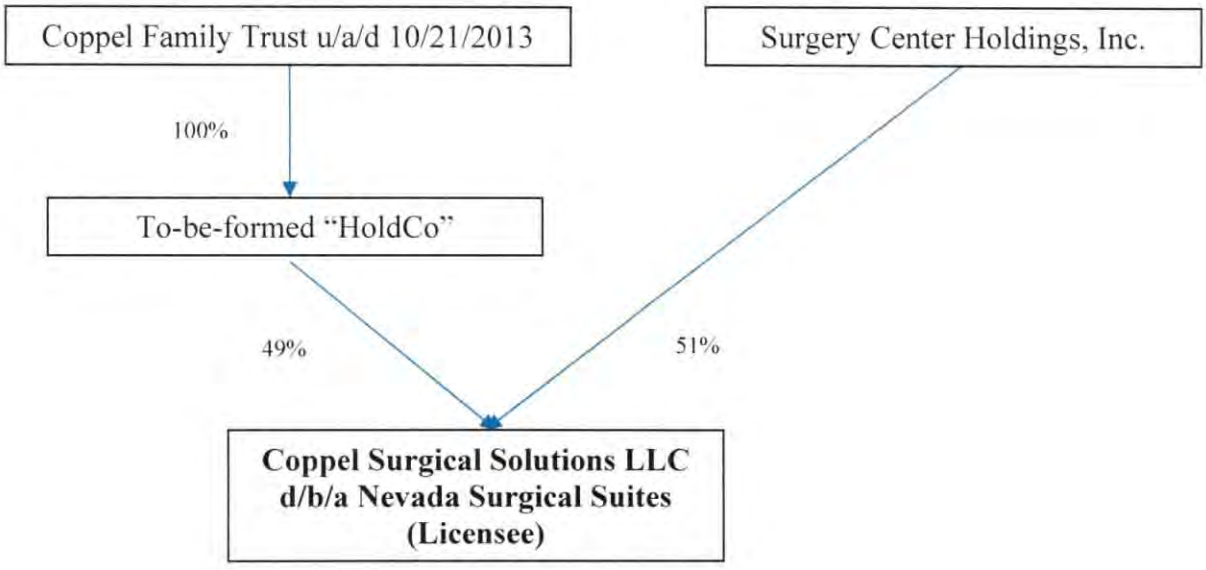
Managing Officer & Medical Director of Licensee, Coppel Surgical Solutions, LLC

- Alain Coppel

VP & Secretary of Administrative Member/Parent Company, Surgery Center Holdings, Inc.

- Jennifer Baldock

Post-Closing Organizational Chart & Ownership Information



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **COPPEL SURGICAL SOLUTIONS LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/24/2012, and is in good standing in this state.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/03/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202311034092156
You may verify this certificate online at http://www.nvsos.gov

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ☑ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☑ Ownership Change*	ASC03466	☑ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Nevada Surgical Suites

Physical Address: 1569 E Flamingo Road

City: Las Vegas State: Nevada Zip: 89119

Mailing Address (if different from physical address): See physical address

City: State: Zip:

Telephone: 702-743-8986 Fax: (702) 476-9500

Contact Email: julie.woodward@nvcpc.com Website https://nevadasurgicalsuites.com/location/

Nevada Business License # NV20121456024

Employed/Contracted Pharmacist Name: Todd Bleak NV Pharmacist License #: 11505

Medical Director Name: Alain Coppel

Days of Operation

☑ Monday	☑ Tuesday	☑ Wednesday	☑ Thursday	☑ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Surgery Center Holdings, Inc.

Corporation/Organization Name: Coppel Surgical Solutions, LLC

Mailing Address: 1569 E Flamingo Road

City: Las Vegas State: Nevada Zip: 89119

Telephone: 702-743-8986 Email: julie.woodward @nvcpc.com

Contact Person Name: Julie Woodward, Administrator

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Todd Bleak, PharmD NV Pharmacist License #: 11505

As the employed/contracted pharmacist, for (ASC/RC Name): Nevada Surgical Suites

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

11-03-2023

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ All Limited Partners who hold 10% or more of the interest.			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jennifer Baldock, Vice President and Secretary of Administrative Member, Surgery Center Holdings, Inc.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Jennifer Baldock

Original signature of Authorized Person (copies or stamps not accepted)

November 3, 2023

Date

Board Use Only	Date Received: 11/13/23	Amount: $500 - Check 28782

Exhibit to Section 9: Ownership & Management

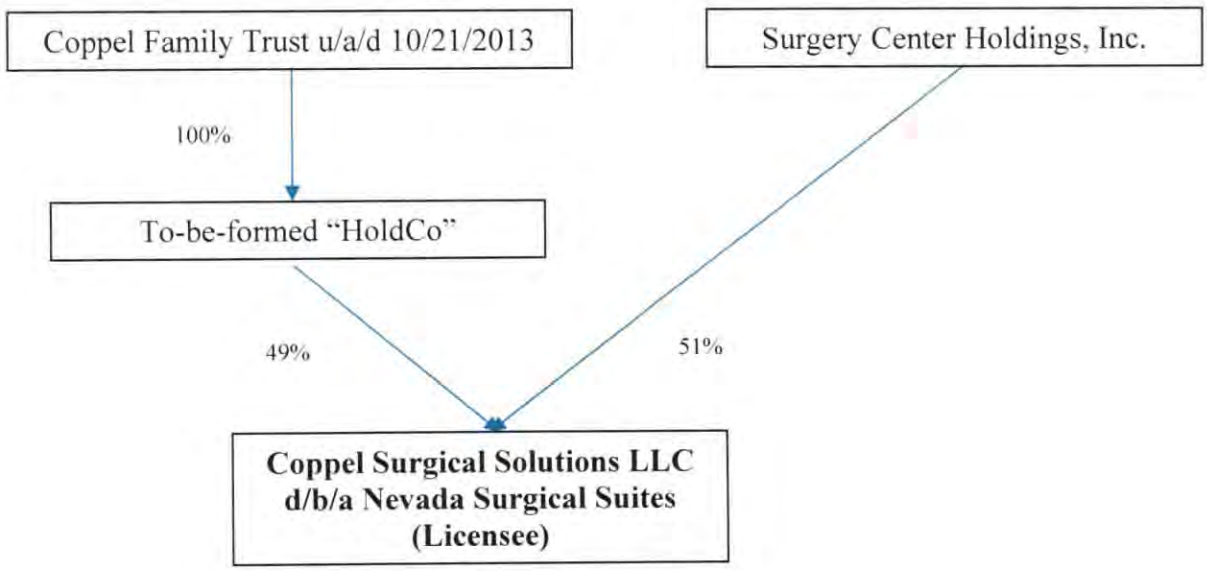
Managing Officer & Medical Director of Licensee, Coppel Surgical Solutions, LLC

- Alain Coppel

VP & Secretary of Administrative Member/Parent Company, Surgery Center Holdings, Inc.

- Jennifer Baldock

Post-Closing Organizational Chart & Ownership Information



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **COPPEL SURGICAL SOLUTIONS LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/24/2012, and is in good standing in this state.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/03/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202311034092156
You may verify this certificate online at http://www.nvsos.gov

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ☑ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☑ Ownership Change*	ASC04489	☑ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Nevada Surgical Suites

Physical Address: 10195 W Twain Avenue

City: Las Vegas State: Nevada Zip: 89147

Mailing Address (if different from physical address): See physical address

City: State: Zip:

Telephone: 702-743-8986 Fax: (702) 476-9500

Contact Email: julie.woodward@nvcpc.com Website https://nevadasurgicalsuites.com/location/

Nevada Business License # NV20121456024

Employed/Contracted Pharmacist Name: Todd Bleak NV Pharmacist License #: 11505

Medical Director Name: Alain Coppel

Days of Operation

☑ Monday	☑ Tuesday	☑ Wednesday	☑ Thursday	☑ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Surgery Center Holdings, Inc.

Corporation/Organization Name: Coppel Surgical Solutions LLC

Mailing Address: 10195 W Twain Avenue

City: Las Vegas State: Nevada Zip: 89147

Telephone: 702-743-8986 Email: julie.woodward@nvcpc.com

Contact Person Name: Julie Woodward, Administrator

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Todd Bleak, PharmD NV Pharmacist License #: 11505

As the employed/contracted pharmacist, for (ASC/RC Name): Nevada Surgical Suites :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

11-03-2023
Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ All Limited Partners who hold 10% or more of the interest.			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jennifer Baldock, Vice President and Secretary of Administrative Member, Surgery Center Holdings, Inc.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Jennifer Baldock

Original signature of Authorized Person (copies or stamps not accepted)

November 3, 2023

Date

Board Use Only	Date Received: 11/13/23	Amount: $500 check 28791

Exhibit to Section 9: Ownership & Management

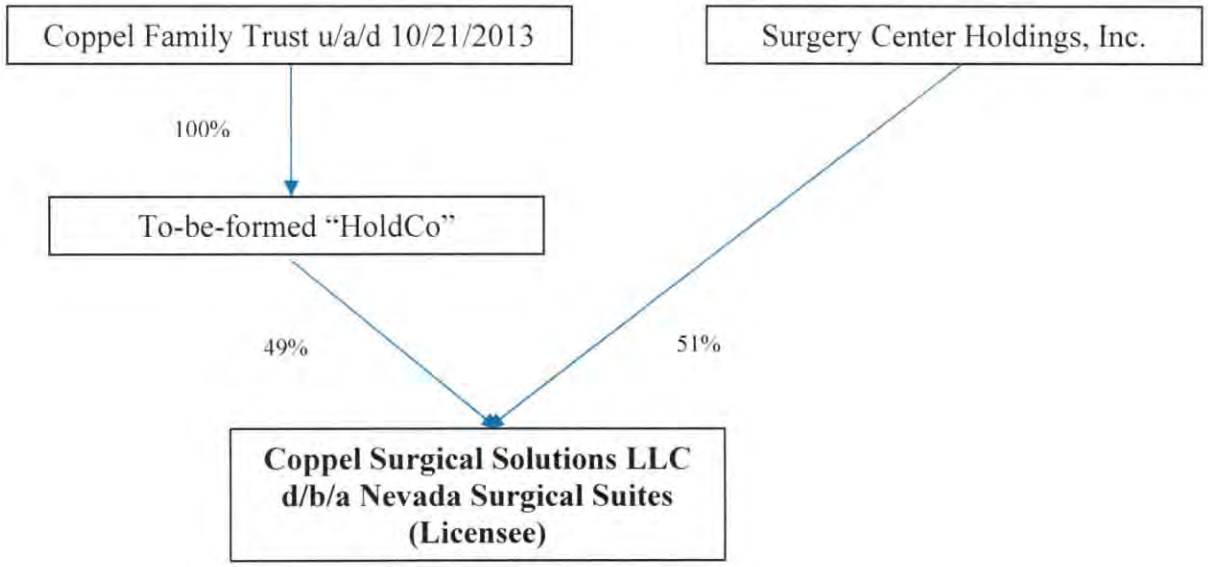
Managing Officer & Medical Director of Licensee, Coppel Surgical Solutions, LLC

- Alain Coppel

VP & Secretary of Administrative Member/Parent Company, Surgery Center Holdings, Inc.

- Jennifer Baldock

Post-Closing Organizational Chart & Ownership Information



SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **COPPEL SURGICAL SOLUTIONS LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/24/2012, and is in good standing in this state.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/03/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202311034092156
You may verify this certificate online at http://www.nvsos.gov

4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (03/17/2023)

Section 1: General Information

First: Gabriela Middle: _____ Last: Castillo R

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] De Haven Ave

City: Sylmar State: CA Zip: 91342

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Section 3: Employment Information

Pharmacy Name: Walgreens License #: 1000069-325

Address: 5011 E Sahara Ave

City: Las Vegas State: NV Zip: 89142

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	
High School Name: Sylmar Senior High School — Graduation Date OR Date GED obtained (mm/yy): 06/06 Address: 13050 Borden Ave City: Sylmar State: CA Zip: 91342		

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	**Initials** JLR	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		✓
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original signature (electronic, copies or stamps not accepted)

8/14/23
Date

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
☐ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☑ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by **a signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Gabriela Castillo R

Print Name

Original Signature, no copies or stamps accepted

8/14/23

Date

Board Use Only	Date Received: 8/16/23	Amount: 50-CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Out-of-State Managing Pharmacist Certification of Employment Hours for Pharmaceutical Technician (PT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PT Employment Hours (NAC 639.240) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PT: GABRIELLA CASTILLO R
PT License # (if applicable): 188103
Pharmacy Manager Name: MEGHEDI GHARAKHANIAN
Pharmacy Manager License #: 64393
Name of Pharmacy: WALGREENS #01606
Pharmacy License #: 52750
Pharmacy Address: 3001 FOOTHILL BLVD
City: LA CRESCENTA
State: CA
Zip: 91214
Time period PT employed (mm/yy-mm/yy): 03/2021-still employed

I certify to the Board that the above-named PT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

TYPING/ENTERING PRESCRIPTIONS
FILLING PRESCRIPTIONS
RETURN TO STOCK MEDICATIONS
CHECKING FOR EXPIRES
CALLING INSURANCE TO RESOLVE PRESCRIPTION ISSUES

Do you certify that the PT is competent to perform the duties of a PT? ☒Yes ☐No
(If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

MEGHEDI GHARAKHANIAN
Print Name (First, Last)

Meghedi
Original Signature (electronic, copies or stamps not accepted)

6/19/2023
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Meghedi Gharakhanian (your name), am the pharmacy manager (your title) for Walgreens pharmacy (name of Pharmacy), located at 3001 Foothill blvd LA Crescenta, CA 91214 (address of Pharmacy). I have worked with the pharmaceutical technician, Gabriella Castillo R (name of technician) listed on this form, and I certify that the statements contained herein are true and correct and contain a full and true account of the information requested.

Meghedi
Original Signature

6/19/2023
Date

Subscribed and Sworn to before me this 19 day of June. 2023

Notary Public Signature

See Attached Jurat

(Seal)

Board Use Only	Date Received: 8/16/23

JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 19 day of June,

20 23 by Meghedi Gharakhanian,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

Signature (Seal)

JORDAN MD MAGOON
Notary Public - California
Los Angeles County
Commission # 2395506
My Comm. Expires Mar 2, 2026

OPTIONAL INFORMATION

DESCRIPTION OF THE ATTACHED DOCUMENT

Out of State Managing
(Title or description of attached document)
Pharmacist certification of Employment Hours for Pharmaceutical Technician
(Title or description of attached document continued)

Number of Pages 2 Document Date 6/19/2023.

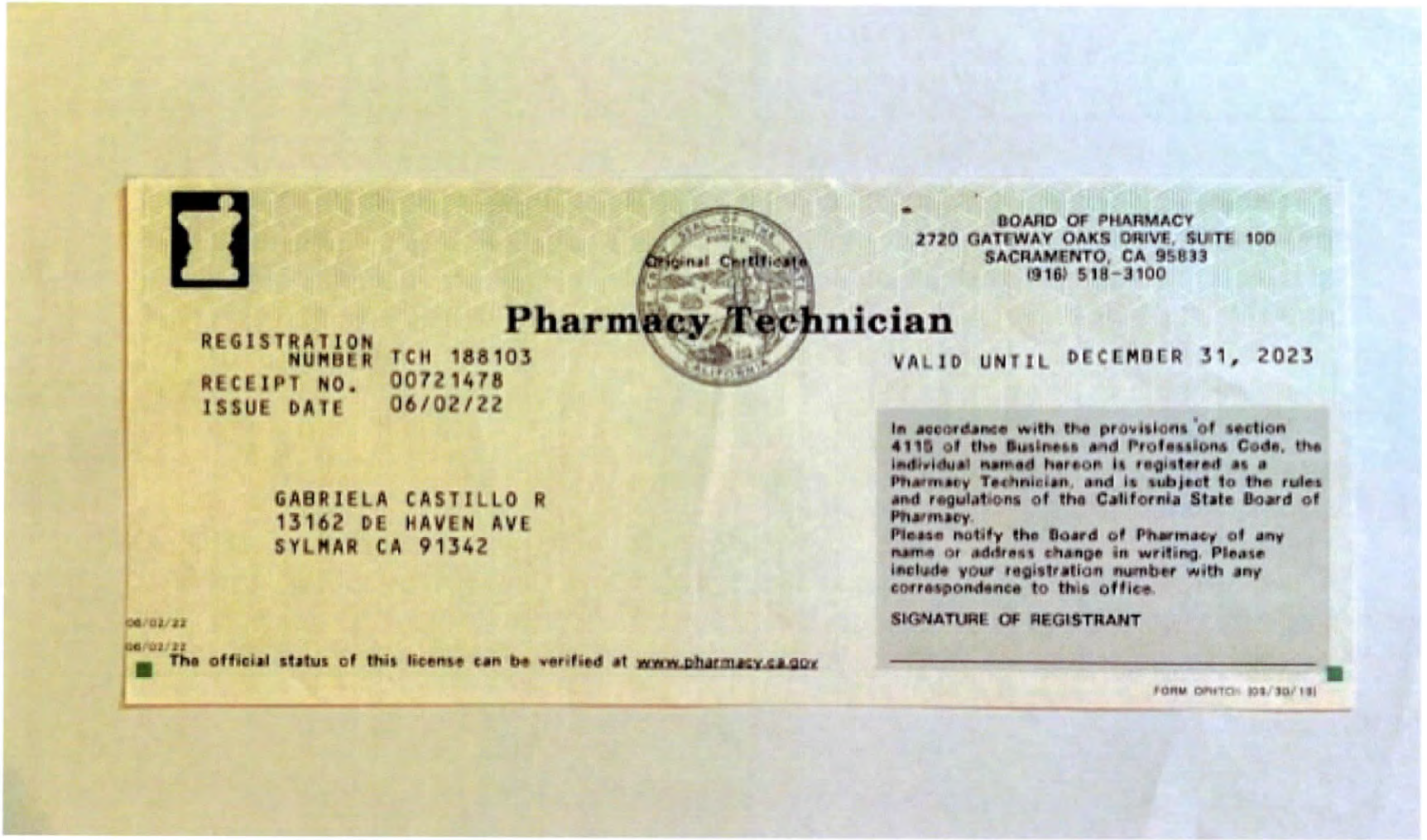
Additional information

INSTRUCTIONS

The wording of all Jurats completed in California after January 1, 2015 must be in the form as set forth within this Jurat. There are no exceptions. If a Jurat to be completed does not follow this form, the notary must correct the verbiage by using a jurat stamp containing the correct wording or attaching a separate jurat form such as this one with does contain the proper wording. In addition, the notary must require an oath or affirmation from the document signer regarding the truthfulness of the contents of the document. The document must be signed AFTER the oath or affirmation. If the document was previously signed, it must be re-signed in front of the notary public during the jurat process.

- State and county information must be the state and county where the document signer(s) personally appeared before the notary public.
- Date of notarization must be the date the signer(s) personally appeared which must also be the same date the jurat process is completed.
- Print the name(s) of the document signer(s) who personally appear at the time of notarization.
- Signature of the notary public must match the signature on file with the office of the county clerk.
- The notary seal impression must be clear and photographically reproducible. Impression must not cover text or lines. If seal impression smudges, re-seal if a sufficient area permits, otherwise complete a different jurat form.
  - ❖ Additional information Is not required but could help to ensure this jurat is not misused or attached to a different document.
  - ❖ Indicate title or type of attached document, number of pages and date.
- Securely attach this document to the signed document with a staple.

2015 Version www.NotaryClasses.com 800-873-9865



BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Original Certificate

Pharmacy Technician

REGISTRATION NUMBER TCH 188103
RECEIPT NO. 00721478
ISSUE DATE 06/02/22

VALID UNTIL DECEMBER 31, 2023

GABRIELA CASTILLO R
13162 DE HAVEN AVE
SYLMAR CA 91342

In accordance with the provisions of section 4115 of the Business and Professions Code, the individual named hereon is registered as a Pharmacy Technician, and is subject to the rules and regulations of the California State Board of Pharmacy.
Please notify the Board of Pharmacy of any name or address change in writing. Please include your registration number with any correspondence to this office.

SIGNATURE OF REGISTRANT

06/02/22

06/02/22

The official status of this license can be verified at www.pharmacy.ca.gov

FORM OPHTCH 09/30/18

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/22/10		CA	Sylmar	Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2215448	Los Angeles Police Department

Reason/Charge
At fault vechicle Accident. Accused of hit and run accident resulting in property damages and loud noise.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

To the best of my recollection, in December of 2009, I was in a vehicle accident in which I was at fault. However, the other party accused me of leaving the scene after I proceeded to drive forward where I deemed it safe to pull over. As a result, I was to appear in court for a hit and run. In the end I was ordered to pay about 600 dollars with an infraction for disturbing the peace and probation.

Although I did not include this important incident that occurred in my past, it was surely not my intention to deliberately omit any information from the Nevada State Board of Pharmacy. It was my honest and understanding and recollection of the events that occured back in the year of 2009/2010 in which I was involved in a car accident that resulted in an infraction.

Since it has been some time since the occurrence, I went ahead and visited the Police Station in California to find more information about my case. There, I was able to get a case number (2215448) and DR number (20100311). The officer attending me described the case notes to me that stated, a hit and run, property damages that were dropped to an infraction and probation. This was new information to me because it was my understanding at the time that I was only charged with an infraction and did not have a hit and run on my record.

In conclusion, I am certain that I have provided all the information in regards to my background. I hope that I have provided more information to clarify my background
and I am allowed to continue with my licensing with the Board of Pharmacy in the state of Nevada.

Sincerely,

Gabriela Castillo R

Original Signature (electronic, copies or stamps not accepted)

12/27/2023

Date

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application

Non-Refundable $50 fee

Rev (01/18/2023)

Section 1: General Information

First: Sammie Middle: Last: Sok

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Jamison Park Ln

City: North Las Vegas State: NV Zip: 89032

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name:

Address:

City: State: Zip:

Name of Program Director:

Section 3: Employment Information

Pharmacy Name: Kabafusion License #: PHY 58826

Address: 17777 Center Court Dr N

City: Cerritos State: CA Zip: 90703

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: Long Beach Poly Graduation Date OR Date GED obtained (mm/yy): 06/99

Address: 1600 Atlantic Ave

City: Long Beach State: CA Zip: 90813

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 7: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		X
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/1/23
Date

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
☐ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☒ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a **signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Sammie Sok

Print Name

Original Signature, no copies or stamps accepted

11/1/23

Date

Board Use Only	Date Received: 11/9/23	Amount: $50 - check 185

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Out-of-State Managing Pharmacist Certification of Employment Hours for Pharmaceutical Technician (PT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PT Employment Hours (NAC 639.240) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PT: Sammie Sok
PT License # (if applicable): TCH 62435
Pharmacy Manager Name: Stephanie Shieh
Pharmacy Manager License #: RPH 71268
Name of Pharmacy: KabaFusion
Pharmacy License #: PHY 58826
Pharmacy Address: 17777 Center Court Dr North Ste 175
City: Cerritos
State: CA
Zip: 90703
Time period PT employed (mm/yy-mm/yy): 08/21 - present

I certify to the Board that the above-named PT has successfully completed 4,000+ hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Fill and label prescriptions
Restock and maintain inventory of supplies
Packaging supplies and drugs
Counting for month end inventory

Do you certify that the PT is competent to perform the duties of a PT? ☒ Yes ☐ No
(If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

Stephanie Shieh
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/2/23
Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Stephanie Shieh (your name), am the pharmacy supervisor (your title) for KabaFusion (name of Pharmacy), located at 17777 Center Court Dr N Cerritos CA 90703 Ste 175 (address of Pharmacy). I have worked with the pharmaceutical technician, Sammie Sok (name of technician) listed on this form, and I certify that the statements contained herein are true and correct and contain a full and true account of the information requested.

Original Signature

11/2/23
Date

Subscribed and Sworn to before me this 02 day of November, 2023

Notary Public Signature

MAYUR JEETENDRABHAI SHAH
Notary Public - California
Los Angeles County
Commission # 2452035
My Comm. Expires Jul 28, 2027

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

Board Use Only	Date Received: 11/9/23

Renewal Certificate

Pharmacy Technician

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

REGISTRATION NUMBER TCH 62435
RECEIPT NO. 31100252

VALID UNTIL MAY 31 2025

SAMMIE SOK
[redacted] BELCHER ST
NORWALK CA 90650

In accordance with the provisions of section 4115 of the Business and Professions Code, the individual named hereon is registered as a Pharmacy Technician, and is subject to the rules and regulations of the California State Board of Pharmacy.

Please notify the Board of Pharmacy of any name or address change in writing. Please include your registration number with any correspondence to this office.

SIGNATURE OF REGISTRANT

/24/23
/24/23

The official status of this license can be verified at www.pharmacy.ca.gov

FORM WPHTCH (10/30/19)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # 2. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/7/08	3/7/08	CA	Long Beach	LA

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1205851	LBPD

Reason/Charge
DUI

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

I was arrested for DUI on 3/7/08. As of right now, the case has been destroyed and closed.

Original Signature (electronic, copies of stamps not accepted)

12/28/23
Date

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

COURTHOUSE ADDRESS:
NORWALK COURTHOUSE 12720 NORWALK BLVD NORWALK, CA 90650

NAME SEARCHED:
SAMMIE SOK

DATE OF BIRTH:
MAY 03, 1981

CERTIFICATE OF CLERK RE: NAME SEARCH RESULTS

I, DAVID W. SLAYTON, Executive Officer/Clerk of Court of the Superior Court of California, County of Los Angeles, do hereby certify that I am the Custodian of Records of the Superior Court of California, County of Los Angeles, and that I have conducted a thorough search of all Court records, excluding those that are sealed pursuant to California Rules of Court, Rule 2.550, or are confidential by law,

from 1999/MAY 03 (YEAR / DATE) to 2023/DECEMBER 28 (YEAR / DATE) for the above-referenced name, and that:

☑ I am unable to provide you with a copy of the case information/case number. The case information requested has been purged and/or destroyed pursuant to Court order. (G.C. 68152)

☐ My search has disclosed "NO CASE FILE" for the aforementioned name.

☐ My search has disclosed that the following case(s) was (were) filed involving the above-referenced name:

LB 8LT00486-01

DATE: 12/28/2023

DAVID W. SLAYTON, Executive Officer/Clerk of Court

By: E. Villalobos
Deputy Clerk

Court Seal

CERTIFICATE OF CLERK – NAME SEARCH RESULTS

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician (PT) Application
Non-Refundable $50 fee

Rev (03/17/2023)

Section 1: General Information

First: Tiffany Middle: Michelle Last: James

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] W lone mountain Rd [redacted]

City: North las vegas State: NV Zip: 89031

Telephone: [redacted] Email [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you have successfully completed an ASHP and Board approved PT school or training program.)

Program/School Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Name of Program Director: _____

Section 3: Employment Information

Pharmacy Name: Walgreens License #: PHR004777

Address: 11509 Abercorn st

City: Savannah State: GA Zip: 31419

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: Jasper High Graduation Date OR Date GED obtained (mm/yy): 06/04

Address: Jasper lane

City: Ridgeland State: SC Zip: 29936

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History	Initials	
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**		
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		✓
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Section 8: You MUST submit the documents below with your application base on your qualifications as a PT.	
Select your qualification as a PT (please check a box).	**Required documents to be submitted with your application.**
☐ The successful completion of an ASHP-approved PT school or training program	a. Provide a copy of the certification of completion of the program.
☒ **Active practice in good standing** in another state as a PT, and the successful completion of at least 1,500 hours of employment as a PT in a pharmacy in that state performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, which must be verified by a **signed affidavit** by the managing pharmacist of the pharmacy.	a. Provide a copy of your PT registration, license, or certificate (if it is a requirement by that state to practice as a PT), which must be current, active, and in good standing. b. Provide the signed affidavit from your managing pharmacist that you have completed at least 1,500 hours of employment as a PT in a pharmacy **in that state** (see form provided in this application).
☐ The successful completion of at least 1,500 hours of training and experience as a registered pharmaceutical technician in training (PTT), performing the duties set forth in paragraph (c) of subsection 3 of NRS 639.1371, in Nevada licensed pharmacies, which must be verified by the managing pharmacist of the pharmacy.	a. Provide the signed form from your managing pharmacist that you have completed 1,500 hours of training and experience in a pharmacy **in this state** as a registered PTT (see form provided in this application).
☐ The successful completion of a pharmaceutical technician training program conducted by a branch of the U.S. Armed Forces, the Indian Health Service of United States Department of Health and Human Services or the U.S. Department of Veterans Affairs.	a. Provide a copy of the certification of completion of the program.

Section 9: Fingerprints for a background check. ALL APPLICANTS MUST COMPLETE THIS SECTION. NRS 639.1371

In addition to the requirements in section 7, submit fingerprints for a background check by following the instructions https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/FP%20Instructions%20NRS%20639.127%20639.1371.pdf

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

TIFFANY JAMES

Print Name

Original Signature, no copies or stamps accepted

11/13/23

Date

Board Use Only	Date Received: _____	Amount: SD-MU-2906367623S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Out-of-State Managing Pharmacist Certification of Employment Hours for Pharmaceutical Technician (PT)

Rev (06/22/2022)

This form cannot be returned by fax or email.
We must have an original signature and fee to process.

Section 1: Certification of PT Employment Hours (NAC 639.240) MUST BE COMPLETED BY THE PHARMACY MANAGER

Name of PT: Tiffany James
PT License # (if applicable): 41988
Pharmacy Manager Name: JOSHUA TRONE
Pharmacy Manager License #: RPH023307
Name of Pharmacy: WALGREENS #5368
Pharmacy License #: PHRE00B477
Pharmacy Address: 11509 Abercorn St.
City: SAVANNAH
State: GA
Zip: 31419
Time period PT employed (mm/yy-mm/yy): 05/21 - 2/22

I certify to the Board that the above-named PT has successfully completed 1500 hours of training and experience performing the tasks of a PT listed in NRS 639.1371 (3)(c) and NAC 639.245(2). The specific training and experience completed is listed below:

Data entry, filling prescriptions, BIN reconciliation, retail sales, simple compounding, giving immunizations,

Do you certify that the PT is competent to perform the duties of a PT? ☒Yes ☐No
(If you answered "No" please explain why below):

I certify under penalty of perjury that the information contained on this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that pursuant to NRS 239.010, this form and any portion thereof is a public record unless otherwise declared confidential by law, and may be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020.

JOSHUA TRONE
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/29/2023
Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of CHATHAM

I, Joshua Trone (your name), am the Pharmacy Manager (your title) for WALGREENS # 5368 (name of Pharmacy), located at 11509 Abercorn St. SAVANNAH, GA 31419 (address of Pharmacy). I have worked with the pharmaceutical technician, Tiffany James (name of technician) listed on this form, and I certify that the statements contained herein are true and correct and contain a full and true account of the information requested.

Original Signature

9/29/2023
Date

Subscribed and Sworn to before me this 29th day of September.

Notary Public Signature

KENISHA CHAMBERS
MY COMM. EXPIRES
(Seal) NOTARY
PUBLIC
JANUARY 24, 2027
CHATHAM COUNTY, GA

Board Use Only	Date Received:

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/2007	12/2015	sc	hardeeville	jasper
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
n/a				
Reason/Charge				
simple accult and battery				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:
was helping a family member during an altercation and the situation became out of control.

Original Signature (electronic, copies or stamps not accepted)

01/18/2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event MUST be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/2011	12/2011	sc	ridgeland	jasper

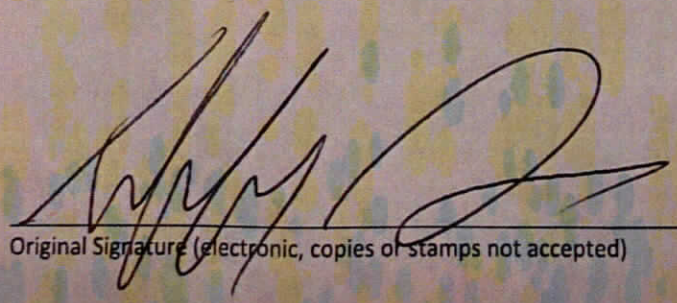
Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
n/a	

Reason/Charge
driving under suspend licence

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:
was not aware that i did not have a licence and was pulled over



Original Signature (electronic, copies or stamps not accepted)

01/18/2024
Date

4CCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☑ Schedule II ☑ Schedule III ☑ Schedule IV ☑ Schedule V

Section 1: Personal Information

First: Terry Middle: Lynn Last: Muratore

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Home Address: [redacted] Paseo Vista Drive

City: Las Vegas State: Nevada Zip: 89128

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: 551-A Specialty: small animal

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Hearts Alive Animal Hospital

Practice Address: 3250 North Decatur Blvd. Suite #:

City: Las Vegas State: Nevada Zip: 89130

Telephone: 702-780-0002 Fax: 702-780-4063 Email: info@heartsalivevillage.org

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
March 2022	pending	NV	Henderson	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	Nevada Board of Veterinary Examiners

Reason/Charge
Records violation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Board of Vet Examiners/Terry Muratore DVM	Arbitration

Name of Business/Industry/Entity
Legacy Animal Hospital

Provide explanation below:

Accused of falsifying rabies certificates. In fact I was exempting certain patients for medical reasons from vaccinations as is allowed under Nevada administrative code section 441A.435 paragraph 4 stating that a veterinarian may exempt a patient from rabies vaccination if the administration of this vaccine could be detrimental to the health of the patient. The code states that the veterinarian must issue a rabies certificate and indicate on the certificate the reason for the exemption. My fault was in not indicating the reason for the exemption on the certificate and was therefore accused of issuing false certificates. Terry

Original Signature (electronic, copies or stamps not accepted)

01-16-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Terry Muratore	01-16-2024
Print Name (First, Last)	Date
	01-16-2024
Original Signature (electronic, copies or stamps not accepted)	Date

Board Use Only: Date Processed: _____	Amount: _____

Terry Muratore

Legal First Name: Terry

Legal Last Name: Muratore

Previous or Other Name(s):

Licenses

License Number	License Category	License Status	Initial Licensure Date	License Expiry Date
0551-A	Veterinarian	Active	Jun-13-1985	Jun-30-2025

Notices, Restrictions and Findings

Type	Effective Date	Summary	Completion Date	Attachments
Disciplinary Finding	Apr-23-2020	File Number: 09-2019DVM-79	Mar-25-2021	Muratore CD 09-2019DVM-79, 11-2019DVM-98, 12-2019DVM-101.pdf
Disciplinary Finding	Apr-23-2020	File Number: 11-2019DVM-98	Mar-25-2021	Muratore CD 09-2019DVM-79, 11-2019DVM-98, 12-2019DVM-101.pdf
Disciplinary Finding	Apr-23-2020	File Number: 12-2019DVM-101	Mar-25-2021	Muratore CD 09-2019DVM-79, 11-2019DVM-98, 12-2019DVM-101.pdf
Disciplinary Finding	Jul-21-2022	Findings of Fact, Conclusions of Law and Order 03-2022DVM-10	N/A	FofCoL 03-2022DVM-10.pdf 9-29-22 Joint Stipulation.pdf

Places of Work

Name	Street Address	City	Postal Code	Start Date	End Date
Legacy Animal Hospital	2591 Windmill Parkway	Henderson	89074	Dec-31-2016	Mar-11-2022

Back To Dashboard

Renewal Application
Controlled Substance

Application Fee : $200.00
Convenience Fee : $10.00
License Number : CS03534
License Type : Controlled Substance
New Expiration Date : 10/31/2022

Personal Information

First Name : TERRY
Middle (initial only) : L
Last Name : MURATORE
License # : CS03534

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Terry Muratore
Military Address :
Street : 2591 Windmill Parkway
Legacy Animal Hospital
Country : United States
City : Henderson
State : Nevada
Zip : 89074
Practice Phone : (702) 263-9004
Practice Fax : (702) 446-8061
Email Address : [redacted]
Sex : Male
Practice License Number:
Specialty:

Child Support Information – Check appropriate answer

- (•) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order.
- ( ) I am **SUBJECT** to a court order for the support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in the Armed Forces of the United States and separated from such service under condition other than dishonorable	( ) Yes (•) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable	( ) Yes (•) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the National Oceanic and Atmospheric Administration of the United States in the capacity of the commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?	( ) Yes (•) No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?	( ) Yes (•) No
2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state?	( ) Yes (•) No
3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whether completed or pending in any state?	( ) Yes (•) No
4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state?	( ) Yes (•) No

Acknowledgement and Declaration

By signing and submitting this renewal application, I certify that: 1. My DEA certificate is CURRENT and reflects my current NV practicing address, and 2. I hold an **active** and **current** Nevada license with my professional licensing board

It is a violation of Nevada Statute to falsify this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certify that all statements made are true and correct.

Signature : Terry Muratore

Date Of Application : 10/13/2020

Please type only the First and Last Name that are listed at the top of the page

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2020 to 10/31/2022	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0.00
	Total :	**$210.00**

Fee and Payment

Payment Method : [redacted]

Application Fees : 200

Reinstatement Fee : 0

Transaction Fee : 10

Late Fees : 0

Reference Number : [redacted]

InvoiceDate : 10/13/2020

Paid

Pay & Submit

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BEFORE THE NEVADA STATE BOARD

OF VETERINARY MEDICAL EXAMINERS

In the Matter of:	)	
	)	**Case Nos. 09-2019DVM-79, 11-2019DVM-98 & 12-2019DVM-101**
TERRY MURATORE, DVM	)	
	)	
License # 0551	)	**CONSENT DECREE**
	)	

The Nevada State Board of Veterinary Medical Examiners (the Board), by and through its Investigating Board Member Ronald Sandoval, DVM (IBM) for case 09-2019DVM-79, Investigating Board Member Betsy Phillips, DVM (IBM2) for case 12-2019DVM-101, and Investigating Board Member Davyd Pelsue, DVM, DACVS (IBM3) for case 11-2019DVM-98 hereby enter into this Consent Decree with Terry Muratore, DVM (License No. 0551). Pursuant to chapter 233B and chapter 638 of the Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC), it is hereby stipulated and agreed, by and between the parties in the above-entitled matter, that this matter shall be settled and resolved upon the following terms:

STIPULATED FACTS AND CONCLUSIONS OF LAW

Dr. Muratore understands the nature of the allegations under consideration by the Board. He acknowledges that the conduct described below constitutes violations of the Nevada Veterinary Practice Act (NRS & NAC 638). He acknowledges that if this matter were to be taken to a disciplinary hearing, the following allegations could be proven and that by acknowledging the same, he is subject to disciplinary action by the Board:

1. At all times pertinent to this matter, Dr. Muratore was licensed as a licensed veterinarian in the State of Nevada, practicing at Legacy Animal Hospital (LAH), 2591 Windmill Parkway in Henderson, Nevada and is, therefore, subject to the jurisdiction of the Board. At all times pertinent to this matter, Dr. Muratore was the owner of and veterinarian-in-charge for LAH.

Facts and Violations Related to Case No. 09-2019DVM-79

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2. On June 10, 2019, the owners of a nine-year-old female spayed Great Dane named Isabella brought her to LAH where Dr. Muratore performed surgery to remove a fatty mass (lipoma) on Isabella's chest. The mass had been first noted at LAH in 2015 and had been monitored since that time. After surgery to remove the mass, Isabella developed a seroma, for which Dr. Muratore performed treatment with bandage changes and antibiotics.

3. On June 15, 2019, Isabella's owner brought her to LAH for a bandage change, and the veterinary assistant who removed the bandage discovered that the surgical site had dehisced and had what she believed was a serious infection. Dr. Muratore was in surgery during this time and communicated through the veterinary assistant with the owners. Because of delays in Dr. Muratore's ability to address the dehiscence, the owner elected to take Isabella to an emergency hospital in the Las Vegas area to have her post-surgical complications addressed.

4. After Isabella's owner made a complaint to the Board, the Board's staff obtained Isabella's medical records from Dr. Muratore and LAH. A review of the records provided by Dr. Muratore and LAH showed:

(a) A lack of assessment of blood work results;

(b) A lack of interpretive findings of radiographs;

(c) A lack of documentation of communications with the owner;

(d) No discussion or concern regarding Isabella's loss of fifteen pounds over the course of treatment; and

(e) Substantive additions and alterations to the records, sometimes modifying records that were years old, that were not properly identified as addenda.

5. In maintaining substandard records and in substantively altering Isabella's medical records without identifying the alterations or additions as such, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

6. In substantively altering Zoey's medical records from the state in which they were originally made, Dr. Muratore harmed the integrity and utility of the records. In so doing, Dr. Muratore violated

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NRS 638.140(1) (Violation of statute or regulation) and NAC 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and AVMA Principles of Veterinary Medical Ethics VII(A).

Facts and Violations Related to Case No. 11-2019DVM-98

7. On August 7, 2019, an owner of a five-year-old male neutered Siberian Husky named Kingsley brought him to LAH where he was seen by Dr. Muratore. The owner explained that Kingsley showed pain in his left ear since being groomed a few days earlier. It was revealed after Kingsley was sedated that he had cotton remaining in both ears from the groomers which had caused bilateral ear infections. After removing the cotton and flushing the ears, Dr. Muratore gave a subcutaneous injection of meloxicam (5.5 mg), and prescribed meloxicam suspension 1.5 mg/ml #10 ml (once a day orally) and Mometamax drops for administration into both ears.

8. On August 13, 2019, the owner returned with Kingsley, reporting that he had been tucking his rear end, sitting and scooting backwards, and acting uncomfortable and gassy. Dr. Muratore noted pain in the lumbar spine on palpation and took three radiographs of the abdomen and lumbar spine. The medical records show no interpretation of the radiographs, and although no specific diagnosis was made, Dr. Muratore treated Kingsley for spinal issues. Dr. Muratore injected meloxicam 5.2 mg subcutaneously and prescribed piroxicam 10 mg #10 (one tablet orally per day) and Dasuquin.

9. On August 14, 2019, the owner brought Kingsley back to LAH where he was again seen by Dr. Muratore. The owner explained that Kingsley remained very uncomfortable in his back and rear area. Dr. Muratore found that Kingsley was guarding his rear. Without performing further diagnostics, Dr. Muratore prescribed tramadol 50 mg #30 (two tablets orally three time a day and to increase to as many as five tablets per dose three times a day) and prednisone 20 mg #30 (one tablet orally twice a day for two days, then ½ tablet twice a day for two days, then ½ tablet once a day for two days, then ½ tablet every other day for three doses).

10. On August 15, 2019, the owner brought Kingsley back to LAH where he was seen by another veterinarian. The owner explained that Kingsley had been passing bloody stool and had screamed out in pain when he tried to rise the previous night. The veterinarian noted that Kingsley could not get comfortable, shifted position persistently, sat profoundly kyphotic, and was propping

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himself up on vertical surfaces. The veterinarian hospitalized Kingsley, instituted intravenous saline (75 ml/hr) and buprenorphine 0.9 ml, injected 0.2 mg acepromazine intramuscularly, and prescribed the oral medications methocarbamol (1000 mg three times a day), famotidine (20 mg twice a day), and metronidazole (500 mg twice a day). After Kingsley chewed out his catheter and attempted to dig out of his kennel, gabapentin (600 mg three times a day) was added to Kingsley's medication regimen. Kingsley also received 25 mg acepromazine orally that evening.

11. Kingsley remained hospitalized, now under the care of Dr. Muratore, for the next two days (August 16 and 17, 2019). Dr. Muratore continued treating Kingsley similarly to the treatments rendered on August 15, 2019, and by August 17, 2019, Kingsley's pain improved enough to send him home.

12. On August 22, 2019, the owner took Kingsley back to see Dr. Muratore, because he wasn't eating and had no bowel movements. Abdominal radiographs revealed a moderate amount of stool in the distal colon and rectum. Kingsley was given an enema, and 2.6 ml Cerenia was injected subcutaneously.

13. On August 23, 2019, as Kingsley's condition worsened and he became profoundly weak and unable to walk, the owner took him to an emergency veterinary facility in the Las Vegas area. The veterinarians there performed diagnostics and determined that Kingsley had a perforated duodenal ulcer and systemic complications related thereto. Despite immediate abdominal surgery to repair the perforated duodenum and aggressive treatment, on August 24, 2019 the owner opted to have Kingsley humanely euthanized due to Kingsley's continued decline. Results of the pre-mortem biopsy of the perforated duodenal ulcer confirmed erosive/ulcerative duodenitis without evidence of neoplasia.

14. Dr. Muratore's treatment of Kingsley lacked any discernable treatment plan. The records do not show that Dr. Muratore ever made a definitive diagnosis, nor did he definitively rule out any particular diagnosis. As Kingsley's condition worsened while in LAH's and Dr. Muratore's care, the records do not reflect any reconsideration of a diagnosis or treatment plan. Dr. Muratore also ordered a corticosteroid to be given without appropriate washout time after treating Kingsley with the two NSAIDs meloxicam and piroxicam. In so doing, Dr. Muratore violated NRS 638.140(5)

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(Incompetence), NRS 638.140(6) (Negligence), NAC 638.045(2) (Negligence), and NAC 638.045(3) (Incompetence).

15. A review of the records Dr. Muratore made regarding his treatment of Kingsley showed that the records were substandard. For example, the records do not contain any analysis of diagnostics, do not always contain TPRs, and did not always record discussions with the owner. In maintaining substandard records, Dr. Muratore violated NRS 638.140(1) (Violation of statute or regulation) and NAC 638.0475 (Medical records).

Facts and Violations Related to Case No. 12-2019DVM-101

16. On March 8, 2019, the owner of a six-year-old female spayed Pug named Zoey brought her to LAH for a second opinion. (Zoey had been seen at another veterinary hospital the previous three days for bleeding from the mouth, and lab work there revealed Zoey had suspected immune-mediated thrombocytopenia (ITP), which caused a dangerously low platelet count. Due to a series of unfortunate events, the owner lacked confidence with the veterinary hospital that diagnosed the ITP, so she took Zoey to LAH for continued treatment.) Dr. Muratore performed an examination and ordered an abdominal ultrasound to rule out obvious abdominal neoplasia before continuing the medications for ITP that had been initiated by the previous veterinary hospital. Over the next month (a total of eight veterinary visits), Zoey was treated by Dr. Muratore, and her ITP was managed successfully.

17. When Zoey's owner filed a complaint with the Board against the veterinarians at the first veterinary hospital where the ITP was initially diagnosed, Zoey's owner provided within her complaint her copy of Zoey's records from LAH.

18. After the Board complaint was initiated, the Board's staff requested a complete copy of Zoey's medical records from Dr. Muratore at LAH.

19. A comparison of the medical records produced to Zoey's owner with the set produced to the Board showed that the records produced to the Board were substantively different and significantly more detailed than the records earlier produced to Zoey's owner. The set of records produced to the Board contained numerous additions and alterations, none of which were noted properly as addenda.

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20. In the course of the Board's investigation, Dr. Muratore admitted that he had substantively altered Zoey's medical records before producing them to the Board.

21. In substantively altering Zoey's medical records and then presenting the altered set of records to the Board's staff as the complete set of Zoey's medical records while knowing that the records were being reviewed as part of an ongoing investigation into a complaint made by Zoey's owner, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

2. In substantively altering Zoey's medical records from the state in which they were originally provided to Zoey's owner, Dr. Muratore essentially created two sets of records for a single patient, thus harming the integrity and utility of the records. In so doing, Dr. Muratore violated NRS 638.140(1) (Violation of statute or regulation) and NAC 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and AVMA Principles of Veterinary Medical Ethics VII(A).

VOLUNTARY WAIVER OF RIGHTS

Dr. Muratore is aware of, understands, and has been advised of the effect of this Consent Decree, which he has carefully read and fully acknowledged. Dr. Muratore had the opportunity to consult with competent counsel of his choice.

Dr. Muratore has freely and voluntarily entered into the Consent Decree, and he is aware of his rights to contest the charges pending against him. These rights include representation by an attorney at his own expense, the right to a public hearing on any charges or allegations formally filed, the right to confront and cross-examine witnesses called to testify against him, the right to present evidence on his own behalf, the right to testify on his own behalf, the right to obtain any other type of formal judicial review of this matter, and any other rights which may be accorded to him pursuant to the provisions of Chapters 233B, 622, 622A, and 638 of the NRS and the NAC. Dr. Muratore is voluntarily waiving all of these rights in exchange for the Board's acceptance of this Consent Decree.

Should the Consent Decree be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Consent Decree or other documents or matters pertaining to the consideration of this Consent Decree shall not unfairly or illegally prejudice the Board or any of

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its members from further participation, consideration, adjudication, or resolution of these proceedings and that no Board member shall be disqualified or challenged for bias.

In consideration of execution of this Consent Decree, Dr. Muratore for himself, his executors, administrators, successors, and assigns hereby releases and forever discharges the State of Nevada, the Nevada State Board of Veterinary Medical Examiners, and each of their members, agents, investigators, and employees in their individual and representative capacities, from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims, and demands whatsoever, known and unknown, in law or equity, that Licensee ever had, now has, may have, or claims to have against any or all of the persons or entities named in this paragraph arising out of or by reason of this investigation, this disciplinary action, this Consent Decree, or its administration.

Dr. Muratore acknowledges that the Consent Decree shall only become effective after both the Board and he have duly executed it. The Consent Decree becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Dr. Muratore enters into this Consent Decree voluntarily after being fully advised of his rights and as to the consequences of this Consent Decree. This Consent Decree embodies the entire agreement reached between the Board and Dr. Muratore. It may not be altered, amended, or modified without the express consent of the parties.

TERMS OF SETTLEMENT

For the purposes of resolving this matter, the parties agree to the following terms and conditions:

1. Dr. Muratore's license (#551-A) shall be on probation for one year commencing on the effective date of this Consent Decree according to the following terms and conditions:

(a) As soon as possible after the effective date of this Consent Decree, the Board shall designate a veterinarian to serve as a practice monitor for Dr. Muratore and LAH. The terms and conditions of the service of the practice monitor shall be:

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(1) At least monthly, the practice monitor shall obtain from LAH and Dr. Muratore a randomized sampling of medical records in such amount as the practice monitor determines necessary to conduct his or her review. The practice monitor shall review the records to determine whether the records comply with NAC 638.0475 and whether the records are in a SOAP format (Subjective–Objective-Assessment-Plan).

(2) After each set of records reviews, the practice monitor shall provide in writing to Dr. Muratore and the IBM an analysis of the records for compliance with subparagraph (1). Where the records comply, the practice monitor shall say so; where the records do not comply, the practice monitor shall identify the deficiencies with particularity. If records are deficient, either the practice monitor or the IBM or both shall discuss the deficiencies with Dr. Muratore with the aim of improving Dr. Muratore's records so that they all comply with subparagraph (1).

(3) If the practice monitor and the IBM do not see substantial improvement and compliance over time, they may bring those concerns to the attention of the Board for further disciplinary action for failure to comply with this Consent Decree, and the Board may thereafter take whatever disciplinary action it deems needed.

(4) Dr. Muratore may petition the Board for early termination of the probationary term at any time after the practice monitor finds that Dr. Muratore's and LAH's records substantially comply with subparagraph (1) for three consecutive months.

(5) Dr. Muratore shall pay all expenses related to the practice monitor's work immediately upon receiving an invoice for such expenses from the practice monitor. Failure to pay the expenses in a timely manner will constitute a breach of this Consent Decree.

(6) Dr. Muratore shall cooperate in good faith with all reasonable requests from the practice monitor to assure that the practice monitor can perform all functions he or she deems needed to conform with this Consent Decree. A failure to cooperate in good faith will constitute a breach of this Consent Decree.

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(b) Dr. Muratore shall comply with all laws, whether federal or state and whether statutory or regulatory, related to the practice of veterinary medicine. Any substantive violations of such laws during the period of probation shall be considered violations of his probation.

2. Dr. Muratore shall pay the Board's attorney fees and investigative costs of $1,999.50 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

3. For the recordkeeping violations noted herein, Dr. Muratore shall pay a fine of $1,000 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

4. Dr. Muratore shall meet with the Board or its representatives upon request and shall cooperate with such representatives in their supervision, monitoring, investigation, or auditing to assure compliance with the terms and conditions of this order.

5. Dr. Muratore will provide to the Board's office written evidence of successful completion of 5 hours of continuing education in medical records, 4 hours of continuing education regarding ethics, and 3 hours of continuing education regarding drug interactions in small animals within 120 days of the date of the Board's approval of this Consent Decree. The 12 hours of continuing education in this paragraph may not be counted toward Dr. Muratore's continuing education requirements for renewal of his license.

6. In the event the IBM is presented with information reasonably indicating that Dr. Muratore has failed to materially comply with any term of this Consent Decree, the IBM (a) may immediately suspend Dr. Muratore's license without further action of the Board and (b) shall inform Dr. Muratore of what he believes to constitute the noncompliance and shall give Dr. Muratore no more than ten days to respond to the IBM describing what actions he intends to take to remedy the noncompliance. If Dr. Muratore cannot or does not satisfy the IBM with his response, the IBM may take such action as the IBM deems necessary to assure compliance by Dr. Muratore, which may include but is not limited to negotiating a resolution or amendment to this Consent Decree, suspending Dr. Muratore's license, commencing additional disciplinary action, and/or taking any other administrative or legal action the

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IBM deems necessary to effectuate compliance with this Consent Decree. Dr. Muratore's failure to comply with any term or condition of this Consent Decree shall also result in further discipline by the Board, up to and potentially including revocation of his license. Board staff may take any and all actions it deems necessary to collect any sums ordered that remain unpaid. If Board staff is required to pursue judicial action to affect such collections, it shall be entitled to recover its attorney's fees and costs incurred in pursuing such judicial action.

Signed and effective this 23 day of April, 2020.

NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

Ronald Sandoval, DVM
Investigating Board Member

DR. TERRY MURATORE

Terry Muratore, DVM
Respondent

ORDER

By a majority vote on April 23, 2020, the Nevada State Board of Veterinary Medical Examiners approved and adopted the terms and conditions set forth in the attached Consent Decree regarding Terry Muratore, DVM.

THIS ORDER IS HEREBY MADE EFFECTIVE this 23 day of April, 2020.

THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

By: _____
STEPHEN DAMONTE, DVM
Board President

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BEFORE THE NEVADA STATE BOARD

OF VETERINARY MEDICAL EXAMINERS

In the Matter of:	**Case Nos. 09-2019DVM-79, 11-2019DVM-98 & 12-2019DVM-101**
TERRY MURATORE, DVM	
License # 0551	**CONSENT DECREE**

The Nevada State Board of Veterinary Medical Examiners (the Board), by and through its Investigating Board Member Ronald Sandoval, DVM (IBM) for case 09-2019DVM-79, Investigating Board Member Betsy Phillips, DVM (IBM2) for case 12-2019DVM-101, and Investigating Board Member Davyd Pelsue, DVM, DACVS (IBM3) for case 11-2019DVM-98 hereby enter into this Consent Decree with Terry Muratore, DVM (License No. 0551). Pursuant to chapter 233B and chapter 638 of the Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC), it is hereby stipulated and agreed, by and between the parties in the above-entitled matter, that this matter shall be settled and resolved upon the following terms:

STIPULATED FACTS AND CONCLUSIONS OF LAW

Dr. Muratore understands the nature of the allegations under consideration by the Board. He acknowledges that the conduct described below constitutes violations of the Nevada Veterinary Practice Act (NRS & NAC 638). He acknowledges that if this matter were to be taken to a disciplinary hearing, the following allegations could be proven and that by acknowledging the same, he is subject to disciplinary action by the Board:

1. At all times pertinent to this matter, Dr. Muratore was licensed as a licensed veterinarian in the State of Nevada, practicing at Legacy Animal Hospital (LAH), 2591 Windmill Parkway in Henderson, Nevada and is, therefore, subject to the jurisdiction of the Board. At all times pertinent to this matter, Dr. Muratore was the owner of and veterinarian-in-charge for LAH.

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5. In maintaining substandard records and in substantively altering Isabella's medical records without identifying the alterations or additions as such, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

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Facts and Violations Related to Case No. 12-2019DVM-101

16. On March 8, 2019, the owner of a six-year-old female spayed Pug named Zoey brought her to LAH for a second opinion. (Zoey had been seen at another veterinary hospital the previous three days for bleeding from the mouth, and lab work there revealed Zoey had suspected immune-mediated thrombocytopenia (ITP), which caused a dangerously low platelet count. Due to a series of unfortunate events, the owner lacked confidence with the veterinary hospital that diagnosed the ITP, so she took Zoey to LAH for continued treatment.) Dr. Muratore performed an examination and ordered an abdominal ultrasound to rule out obvious abdominal neoplasia before continuing the medications for ITP that had been initiated by the previous veterinary hospital. Over the next month (a total of eight veterinary visits), Zoey was treated by Dr. Muratore, and her ITP was managed successfully.

17. When Zoey's owner filed a complaint with the Board against the veterinarians at the first veterinary hospital where the ITP was initially diagnosed, Zoey's owner provided within her complaint her copy of Zoey's records from LAH.

18. After the Board complaint was initiated, the Board's staff requested a complete copy of Zoey's medical records from Dr. Muratore at LAH.

19. A comparison of the medical records produced to Zoey's owner with the set produced to the Board showed that the records produced to the Board were substantively different and significantly more detailed than the records earlier produced to Zoey's owner. The set of records produced to the Board contained numerous additions and alterations, none of which were noted properly as addenda.

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20. In the course of the Board's investigation, Dr. Muratore admitted that he had substantively altered Zoey's medical records before producing them to the Board.

21. In substantively altering Zoey's medical records and then presenting the altered set of records to the Board's staff as the complete set of Zoey's medical records while knowing that the records were being reviewed as part of an ongoing investigation into a complaint made by Zoey's owner, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

2. In substantively altering Zoey's medical records from the state in which they were originally provided to Zoey's owner, Dr. Muratore essentially created two sets of records for a single patient, thus harming the integrity and utility of the records. In so doing, Dr. Muratore violated NRS 638.140(1) (Violation of statute or regulation) and NAC 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and AVMA Principles of Veterinary Medical Ethics VII(A).

VOLUNTARY WAIVER OF RIGHTS

Dr. Muratore is aware of, understands, and has been advised of the effect of this Consent Decree, which he has carefully read and fully acknowledged. Dr. Muratore had the opportunity to consult with competent counsel of his choice.

Dr. Muratore has freely and voluntarily entered into the Consent Decree, and he is aware of his rights to contest the charges pending against him. These rights include representation by an attorney at his own expense, the right to a public hearing on any charges or allegations formally filed, the right to confront and cross-examine witnesses called to testify against him, the right to present evidence on his own behalf, the right to testify on his own behalf, the right to obtain any other type of formal judicial review of this matter, and any other rights which may be accorded to him pursuant to the provisions of Chapters 233B, 622, 622A, and 638 of the NRS and the NAC. Dr. Muratore is voluntarily waiving all of these rights in exchange for the Board's acceptance of this Consent Decree.

Should the Consent Decree be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Consent Decree or other documents or matters pertaining to the consideration of this Consent Decree shall not unfairly or illegally prejudice the Board or any of

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its members from further participation, consideration, adjudication, or resolution of these proceedings and that no Board member shall be disqualified or challenged for bias.

In consideration of execution of this Consent Decree, Dr. Muratore for himself, his executors, administrators, successors, and assigns hereby releases and forever discharges the State of Nevada, the Nevada State Board of Veterinary Medical Examiners, and each of their members, agents, investigators, and employees in their individual and representative capacities, from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims, and demands whatsoever, known and unknown, in law or equity, that Licensee ever had, now has, may have, or claims to have against any or all of the persons or entities named in this paragraph arising out of or by reason of this investigation, this disciplinary action, this Consent Decree, or its administration.

Dr. Muratore acknowledges that the Consent Decree shall only become effective after both the Board and he have duly executed it. The Consent Decree becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Dr. Muratore enters into this Consent Decree voluntarily after being fully advised of his rights and as to the consequences of this Consent Decree. This Consent Decree embodies the entire agreement reached between the Board and Dr. Muratore. It may not be altered, amended, or modified without the express consent of the parties.

TERMS OF SETTLEMENT

For the purposes of resolving this matter, the parties agree to the following terms and conditions:

1. Dr. Muratore's license (#551-A) shall be on probation for one year commencing on the effective date of this Consent Decree according to the following terms and conditions:

(a) As soon as possible after the effective date of this Consent Decree, the Board shall designate a veterinarian to serve as a practice monitor for Dr. Muratore and LAH. The terms and conditions of the service of the practice monitor shall be:

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(1) At least monthly, the practice monitor shall obtain from LAH and Dr. Muratore a randomized sampling of medical records in such amount as the practice monitor determines necessary to conduct his or her review. The practice monitor shall review the records to determine whether the records comply with NAC 638.0475 and whether the records are in a SOAP format (Subjective–Objective-Assessment-Plan).

(2) After each set of records reviews, the practice monitor shall provide in writing to Dr. Muratore and the IBM an analysis of the records for compliance with subparagraph (1). Where the records comply, the practice monitor shall say so; where the records do not comply, the practice monitor shall identify the deficiencies with particularity. If records are deficient, either the practice monitor or the IBM or both shall discuss the deficiencies with Dr. Muratore with the aim of improving Dr. Muratore's records so that they all comply with subparagraph (1).

(3) If the practice monitor and the IBM do not see substantial improvement and compliance over time, they may bring those concerns to the attention of the Board for further disciplinary action for failure to comply with this Consent Decree, and the Board may thereafter take whatever disciplinary action it deems needed.

(4) Dr. Muratore may petition the Board for early termination of the probationary term at any time after the practice monitor finds that Dr. Muratore's and LAH's records substantially comply with subparagraph (1) for three consecutive months.

(5) Dr. Muratore shall pay all expenses related to the practice monitor's work immediately upon receiving an invoice for such expenses from the practice monitor. Failure to pay the expenses in a timely manner will constitute a breach of this Consent Decree.

(6) Dr. Muratore shall cooperate in good faith with all reasonable requests from the practice monitor to assure that the practice monitor can perform all functions he or she deems needed to conform with this Consent Decree. A failure to cooperate in good faith will constitute a breach of this Consent Decree.

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(b) Dr. Muratore shall comply with all laws, whether federal or state and whether statutory or regulatory, related to the practice of veterinary medicine. Any substantive violations of such laws during the period of probation shall be considered violations of his probation.

2. Dr. Muratore shall pay the Board's attorney fees and investigative costs of $1,999.50 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

3. For the recordkeeping violations noted herein, Dr. Muratore shall pay a fine of $1,000 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

4. Dr. Muratore shall meet with the Board or its representatives upon request and shall cooperate with such representatives in their supervision, monitoring, investigation, or auditing to assure compliance with the terms and conditions of this order.

5. Dr. Muratore will provide to the Board's office written evidence of successful completion of 5 hours of continuing education in medical records, 4 hours of continuing education regarding ethics, and 3 hours of continuing education regarding drug interactions in small animals within 120 days of the date of the Board's approval of this Consent Decree. The 12 hours of continuing education in this paragraph may not be counted toward Dr. Muratore's continuing education requirements for renewal of his license.

6. In the event the IBM is presented with information reasonably indicating that Dr. Muratore has failed to materially comply with any term of this Consent Decree, the IBM (a) may immediately suspend Dr. Muratore's license without further action of the Board and (b) shall inform Dr. Muratore of what he believes to constitute the noncompliance and shall give Dr. Muratore no more than ten days to respond to the IBM describing what actions he intends to take to remedy the noncompliance. If Dr. Muratore cannot or does not satisfy the IBM with his response, the IBM may take such action as the IBM deems necessary to assure compliance by Dr. Muratore, which may include but is not limited to negotiating a resolution or amendment to this Consent Decree, suspending Dr. Muratore's license, commencing additional disciplinary action, and/or taking any other administrative or legal action the

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IBM deems necessary to effectuate compliance with this Consent Decree. Dr. Muratore's failure to comply with any term or condition of this Consent Decree shall also result in further discipline by the Board, up to and potentially including revocation of his license. Board staff may take any and all actions it deems necessary to collect any sums ordered that remain unpaid. If Board staff is required to pursue judicial action to affect such collections, it shall be entitled to recover its attorney's fees and costs incurred in pursuing such judicial action.

Signed and effective this 23 day of April, 2020.

NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

Ronald Sandoval, DVM
Investigating Board Member

DR. TERRY MURATORE

Terry Muratore, DVM
Respondent

ORDER

By a majority vote on April 23, 2020, the Nevada State Board of Veterinary Medical Examiners approved and adopted the terms and conditions set forth in the attached Consent Decree regarding Terry Muratore, DVM.

THIS ORDER IS HEREBY MADE EFFECTIVE this 23 day of April, 2020.

THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

By: _____
STEPHEN DAMONTE, DVM
Board President

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BEFORE THE NEVADA STATE BOARD

OF VETERINARY MEDICAL EXAMINERS

In the Matter of:	)	
	)	**Case Nos. 09-2019DVM-79, 11-2019DVM-98 &**
TERRY MURATORE, DVM	)	**12-2019DVM-101**
	)	
License # 0551	)	**CONSENT DECREE**
	)	

The Nevada State Board of Veterinary Medical Examiners (the Board), by and through its Investigating Board Member Ronald Sandoval, DVM (IBM) for case 09-2019DVM-79, Investigating Board Member Betsy Phillips, DVM (IBM2) for case 12-2019DVM-101, and Investigating Board Member Davyd Pelsue, DVM, DACVS (IBM3) for case 11-2019DVM-98 hereby enter into this Consent Decree with Terry Muratore, DVM (License No. 0551). Pursuant to chapter 233B and chapter 638 of the Nevada Revised Statutes (NRS) and Nevada Administrative Code (NAC), it is hereby stipulated and agreed, by and between the parties in the above-entitled matter, that this matter shall be settled and resolved upon the following terms:

STIPULATED FACTS AND CONCLUSIONS OF LAW

Dr. Muratore understands the nature of the allegations under consideration by the Board. He acknowledges that the conduct described below constitutes violations of the Nevada Veterinary Practice Act (NRS & NAC 638). He acknowledges that if this matter were to be taken to a disciplinary hearing, the following allegations could be proven and that by acknowledging the same, he is subject to disciplinary action by the Board:

1. At all times pertinent to this matter, Dr. Muratore was licensed as a licensed veterinarian in the State of Nevada, practicing at Legacy Animal Hospital (LAH), 2591 Windmill Parkway in Henderson, Nevada and is, therefore, subject to the jurisdiction of the Board. At all times pertinent to this matter, Dr. Muratore was the owner of and veterinarian-in-charge for LAH.

Facts and Violations Related to Case No. 09-2019DVM-79

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2. On June 10, 2019, the owners of a nine-year-old female spayed Great Dane named Isabella brought her to LAH where Dr. Muratore performed surgery to remove a fatty mass (lipoma) on Isabella's chest. The mass had been first noted at LAH in 2015 and had been monitored since that time. After surgery to remove the mass, Isabella developed a seroma, for which Dr. Muratore performed treatment with bandage changes and antibiotics.

3. On June 15, 2019, Isabella's owner brought her to LAH for a bandage change, and the veterinary assistant who removed the bandage discovered that the surgical site had dehisced and had what she believed was a serious infection. Dr. Muratore was in surgery during this time and communicated through the veterinary assistant with the owners. Because of delays in Dr. Muratore's ability to address the dehiscence, the owner elected to take Isabella to an emergency hospital in the Las Vegas area to have her post-surgical complications addressed.

4. After Isabella's owner made a complaint to the Board, the Board's staff obtained Isabella's medical records from Dr. Muratore and LAH. A review of the records provided by Dr. Muratore and LAH showed:

(a) A lack of assessment of blood work results;

(b) A lack of interpretive findings of radiographs;

(c) A lack of documentation of communications with the owner;

(d) No discussion or concern regarding Isabella's loss of fifteen pounds over the course of treatment; and

(e) Substantive additions and alterations to the records, sometimes modifying records that were years old, that were not properly identified as addenda.

5. In maintaining substandard records and in substantively altering Isabella's medical records without identifying the alterations or additions as such, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

6. In substantively altering Zoey's medical records from the state in which they were originally made, Dr. Muratore harmed the integrity and utility of the records. In so doing, Dr. Muratore violated

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NRS 638.140(1) (Violation of statute or regulation) and NAC 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and AVMA Principles of Veterinary Medical Ethics VII(A).

Facts and Violations Related to Case No. 11-2019DVM-98

7. On August 7, 2019, an owner of a five-year-old male neutered Siberian Husky named Kingsley brought him to LAH where he was seen by Dr. Muratore. The owner explained that Kingsley showed pain in his left ear since being groomed a few days earlier. It was revealed after Kingsley was sedated that he had cotton remaining in both ears from the groomers which had caused bilateral ear infections. After removing the cotton and flushing the ears, Dr. Muratore gave a subcutaneous injection of meloxicam (5.5 mg), and prescribed meloxicam suspension 1.5 mg/ml #10 ml (once a day orally) and Mometamax drops for administration into both ears.

8. On August 13, 2019, the owner returned with Kingsley, reporting that he had been tucking his rear end, sitting and scooting backwards, and acting uncomfortable and gassy. Dr. Muratore noted pain in the lumbar spine on palpation and took three radiographs of the abdomen and lumbar spine. The medical records show no interpretation of the radiographs, and although no specific diagnosis was made, Dr. Muratore treated Kingsley for spinal issues. Dr. Muratore injected meloxicam 5.2 mg subcutaneously and prescribed piroxicam 10 mg #10 (one tablet orally per day) and Dasuquin.

9. On August 14, 2019, the owner brought Kingsley back to LAH where he was again seen by Dr. Muratore. The owner explained that Kingsley remained very uncomfortable in his back and rear area. Dr. Muratore found that Kingsley was guarding his rear. Without performing further diagnostics, Dr. Muratore prescribed tramadol 50 mg #30 (two tablets orally three time a day and to increase to as many as five tablets per dose three times a day) and prednisone 20 mg #30 (one tablet orally twice a day for two days, then ½ tablet twice a day for two days, then ½ tablet once a day for two days, then ½ tablet every other day for three doses).

10. On August 15, 2019, the owner brought Kingsley back to LAH where he was seen by another veterinarian. The owner explained that Kingsley had been passing bloody stool and had screamed out in pain when he tried to rise the previous night. The veterinarian noted that Kingsley could not get comfortable, shifted position persistently, sat profoundly kyphotic, and was propping

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himself up on vertical surfaces. The veterinarian hospitalized Kingsley, instituted intravenous saline (75 ml/hr) and buprenorphine 0.9 ml, injected 0.2 mg acepromazine intramuscularly, and prescribed the oral medications methocarbamol (1000 mg three times a day), famotidine (20 mg twice a day), and metronidazole (500 mg twice a day). After Kingsley chewed out his catheter and attempted to dig out of his kennel, gabapentin (600 mg three times a day) was added to Kingsley's medication regimen. Kingsley also received 25 mg acepromazine orally that evening.

11. Kingsley remained hospitalized, now under the care of Dr. Muratore, for the next two days (August 16 and 17, 2019). Dr. Muratore continued treating Kingsley similarly to the treatments rendered on August 15, 2019, and by August 17, 2019, Kingsley's pain improved enough to send him home.

12. On August 22, 2019, the owner took Kingsley back to see Dr. Muratore, because he wasn't eating and had no bowel movements. Abdominal radiographs revealed a moderate amount of stool in the distal colon and rectum. Kingsley was given an enema, and 2.6 ml Cerenia was injected subcutaneously.

13. On August 23, 2019, as Kingsley's condition worsened and he became profoundly weak and unable to walk, the owner took him to an emergency veterinary facility in the Las Vegas area. The veterinarians there performed diagnostics and determined that Kingsley had a perforated duodenal ulcer and systemic complications related thereto. Despite immediate abdominal surgery to repair the perforated duodenum and aggressive treatment, on August 24, 2019 the owner opted to have Kingsley humanely euthanized due to Kingsley's continued decline. Results of the pre-mortem biopsy of the perforated duodenal ulcer confirmed erosive/ulcerative duodenitis without evidence of neoplasia.

14. Dr. Muratore's treatment of Kingsley lacked any discernable treatment plan. The records do not show that Dr. Muratore ever made a definitive diagnosis, nor did he definitively rule out any particular diagnosis. As Kingsley's condition worsened while in LAH's and Dr. Muratore's care, the records do not reflect any reconsideration of a diagnosis or treatment plan. Dr. Muratore also ordered a corticosteroid to be given without appropriate washout time after treating Kingsley with the two NSAIDs meloxicam and piroxicam. In so doing, Dr. Muratore violated NRS 638.140(5)

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(Incompetence), NRS 638.140(6) (Negligence), NAC 638.045(2) (Negligence), and NAC 638.045(3) (Incompetence).

15. A review of the records Dr. Muratore made regarding his treatment of Kingsley showed that the records were substandard. For example, the records do not contain any analysis of diagnostics, do not always contain TPRs, and did not always record discussions with the owner. In maintaining substandard records, Dr. Muratore violated NRS 638.140(1) (Violation of statute or regulation) and NAC 638.0475 (Medical records).

Facts and Violations Related to Case No. 12-2019DVM-101

16. On March 8, 2019, the owner of a six-year-old female spayed Pug named Zoey brought her to LAH for a second opinion. (Zoey had been seen at another veterinary hospital the previous three days for bleeding from the mouth, and lab work there revealed Zoey had suspected immune-mediated thrombocytopenia (ITP), which caused a dangerously low platelet count. Due to a series of unfortunate events, the owner lacked confidence with the veterinary hospital that diagnosed the ITP, so she took Zoey to LAH for continued treatment.) Dr. Muratore performed an examination and ordered an abdominal ultrasound to rule out obvious abdominal neoplasia before continuing the medications for ITP that had been initiated by the previous veterinary hospital. Over the next month (a total of eight veterinary visits), Zoey was treated by Dr. Muratore, and her ITP was managed successfully.

17. When Zoey's owner filed a complaint with the Board against the veterinarians at the first veterinary hospital where the ITP was initially diagnosed, Zoey's owner provided within her complaint her copy of Zoey's records from LAH.

18. After the Board complaint was initiated, the Board's staff requested a complete copy of Zoey's medical records from Dr. Muratore at LAH.

19. A comparison of the medical records produced to Zoey's owner with the set produced to the Board showed that the records produced to the Board were substantively different and significantly more detailed than the records earlier produced to Zoey's owner. The set of records produced to the Board contained numerous additions and alterations, none of which were noted properly as addenda.

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20. In the course of the Board's investigation, Dr. Muratore admitted that he had substantively altered Zoey's medical records before producing them to the Board.

21. In substantively altering Zoey's medical records and then presenting the altered set of records to the Board's staff as the complete set of Zoey's medical records while knowing that the records were being reviewed as part of an ongoing investigation into a complaint made by Zoey's owner, Dr. Muratore violated Nevada Revised Statutes (NRS) 638.140(1) (Violation of statute or regulation) and Nevada Administrative Code (NAC) 638.0475 (Medical records).

2. In substantively altering Zoey's medical records from the state in which they were originally provided to Zoey's owner, Dr. Muratore essentially created two sets of records for a single patient, thus harming the integrity and utility of the records. In so doing, Dr. Muratore violated NRS 638.140(1) (Violation of statute or regulation) and NAC 638.046 (Violation of AVMA Principles of Veterinary Medical Ethics) and AVMA Principles of Veterinary Medical Ethics VII(A).

VOLUNTARY WAIVER OF RIGHTS

Dr. Muratore is aware of, understands, and has been advised of the effect of this Consent Decree, which he has carefully read and fully acknowledged. Dr. Muratore had the opportunity to consult with competent counsel of his choice.

Dr. Muratore has freely and voluntarily entered into the Consent Decree, and he is aware of his rights to contest the charges pending against him. These rights include representation by an attorney at his own expense, the right to a public hearing on any charges or allegations formally filed, the right to confront and cross-examine witnesses called to testify against him, the right to present evidence on his own behalf, the right to testify on his own behalf, the right to obtain any other type of formal judicial review of this matter, and any other rights which may be accorded to him pursuant to the provisions of Chapters 233B, 622, 622A, and 638 of the NRS and the NAC. Dr. Muratore is voluntarily waiving all of these rights in exchange for the Board's acceptance of this Consent Decree.

Should the Consent Decree be rejected by the Board, it is agreed that presentation to and consideration by the Board of such proposed Consent Decree or other documents or matters pertaining to the consideration of this Consent Decree shall not unfairly or illegally prejudice the Board or any of

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its members from further participation, consideration, adjudication, or resolution of these proceedings and that no Board member shall be disqualified or challenged for bias.

In consideration of execution of this Consent Decree, Dr. Muratore for himself, his executors, administrators, successors, and assigns hereby releases and forever discharges the State of Nevada, the Nevada State Board of Veterinary Medical Examiners, and each of their members, agents, investigators, and employees in their individual and representative capacities, from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims, and demands whatsoever, known and unknown, in law or equity, that Licensee ever had, now has, may have, or claims to have against any or all of the persons or entities named in this paragraph arising out of or by reason of this investigation, this disciplinary action, this Consent Decree, or its administration.

Dr. Muratore acknowledges that the Consent Decree shall only become effective after both the Board and he have duly executed it. The Consent Decree becomes a public document and will be reported to the National Veterinary Disciplinary Database of the American Association of Veterinary State Boards (AAVSB).

Dr. Muratore enters into this Consent Decree voluntarily after being fully advised of his rights and as to the consequences of this Consent Decree. This Consent Decree embodies the entire agreement reached between the Board and Dr. Muratore. It may not be altered, amended, or modified without the express consent of the parties.

TERMS OF SETTLEMENT

For the purposes of resolving this matter, the parties agree to the following terms and conditions:

1. Dr. Muratore's license (#551-A) shall be on probation for one year commencing on the effective date of this Consent Decree according to the following terms and conditions:

(a) As soon as possible after the effective date of this Consent Decree, the Board shall designate a veterinarian to serve as a practice monitor for Dr. Muratore and LAH. The terms and conditions of the service of the practice monitor shall be:

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(1) At least monthly, the practice monitor shall obtain from LAH and Dr. Muratore a randomized sampling of medical records in such amount as the practice monitor determines necessary to conduct his or her review. The practice monitor shall review the records to determine whether the records comply with NAC 638.0475 and whether the records are in a SOAP format (Subjective–Objective-Assessment-Plan).

(2) After each set of records reviews, the practice monitor shall provide in writing to Dr. Muratore and the IBM an analysis of the records for compliance with subparagraph (1). Where the records comply, the practice monitor shall say so; where the records do not comply, the practice monitor shall identify the deficiencies with particularity. If records are deficient, either the practice monitor or the IBM or both shall discuss the deficiencies with Dr. Muratore with the aim of improving Dr. Muratore's records so that they all comply with subparagraph (1).

(3) If the practice monitor and the IBM do not see substantial improvement and compliance over time, they may bring those concerns to the attention of the Board for further disciplinary action for failure to comply with this Consent Decree, and the Board may thereafter take whatever disciplinary action it deems needed.

(4) Dr. Muratore may petition the Board for early termination of the probationary term at any time after the practice monitor finds that Dr. Muratore's and LAH's records substantially comply with subparagraph (1) for three consecutive months.

(5) Dr. Muratore shall pay all expenses related to the practice monitor's work immediately upon receiving an invoice for such expenses from the practice monitor. Failure to pay the expenses in a timely manner will constitute a breach of this Consent Decree.

(6) Dr. Muratore shall cooperate in good faith with all reasonable requests from the practice monitor to assure that the practice monitor can perform all functions he or she deems needed to conform with this Consent Decree. A failure to cooperate in good faith will constitute a breach of this Consent Decree.

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(b) Dr. Muratore shall comply with all laws, whether federal or state and whether statutory or regulatory, related to the practice of veterinary medicine. Any substantive violations of such laws during the period of probation shall be considered violations of his probation.

2. Dr. Muratore shall pay the Board's attorney fees and investigative costs of $1,999.50 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

3. For the recordkeeping violations noted herein, Dr. Muratore shall pay a fine of $1,000 by check or money order made payable to "Nevada State Board of Veterinary Medical Examiners" which must be received by the Board's office within 30 days of the effective date of this Consent Decree.

4. Dr. Muratore shall meet with the Board or its representatives upon request and shall cooperate with such representatives in their supervision, monitoring, investigation, or auditing to assure compliance with the terms and conditions of this order.

5. Dr. Muratore will provide to the Board's office written evidence of successful completion of 5 hours of continuing education in medical records, 4 hours of continuing education regarding ethics, and 3 hours of continuing education regarding drug interactions in small animals within 120 days of the date of the Board's approval of this Consent Decree. The 12 hours of continuing education in this paragraph may not be counted toward Dr. Muratore's continuing education requirements for renewal of his license.

6. In the event the IBM is presented with information reasonably indicating that Dr. Muratore has failed to materially comply with any term of this Consent Decree, the IBM (a) may immediately suspend Dr. Muratore's license without further action of the Board and (b) shall inform Dr. Muratore of what he believes to constitute the noncompliance and shall give Dr. Muratore no more than ten days to respond to the IBM describing what actions he intends to take to remedy the noncompliance. If Dr. Muratore cannot or does not satisfy the IBM with his response, the IBM may take such action as the IBM deems necessary to assure compliance by Dr. Muratore, which may include but is not limited to negotiating a resolution or amendment to this Consent Decree, suspending Dr. Muratore's license, commencing additional disciplinary action, and/or taking any other administrative or legal action the

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IBM deems necessary to effectuate compliance with this Consent Decree. Dr. Muratore's failure to comply with any term or condition of this Consent Decree shall also result in further discipline by the Board, up to and potentially including revocation of his license. Board staff may take any and all actions it deems necessary to collect any sums ordered that remain unpaid. If Board staff is required to pursue judicial action to affect such collections, it shall be entitled to recover its attorney's fees and costs incurred in pursuing such judicial action.

Signed and effective this 23 day of April, 2020.

NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

Ronald Sandoval, DVM
Investigating Board Member

DR. TERRY MURATORE

Terry Muratore, DVM
Respondent

ORDER

By a majority vote on April 23, 2020, the Nevada State Board of Veterinary Medical Examiners approved and adopted the terms and conditions set forth in the attached Consent Decree regarding Terry Muratore, DVM.

THIS ORDER IS HEREBY MADE EFFECTIVE this 23 day of April, 2020.

THE NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

By: STEPHEN DAMONTE, DVM
Board President

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR VETERINARIAN AUTHORITY TO DISPENSE DRUGS

Non-Refundable $150 fee

Rev (06/09/2021)

What types of drug(s) will you be dispensing?

- [x] Dangerous Drugs AND Controlled Substances
- [ ] Dangerous Drugs ONLY

Section 1: Personal Information

First: Terry Middle: Lynn Last: Muratore

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Home Address: [redacted] Paseo Vitsta Drive

City: Las Vegas State: NV Zip: 89128

Telephone: [redacted] Email: [redacted]

Degree: DVM Practitioner License #: 551

(You MUST have a current and active license with your respective BOARD to apply for and maintain a dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Hearts Alive Village Animal Clinic

Practice Address: 3250 North Decatur Blvd Suite #:

City: North Las Vegas State: NV Zip: 89130

Telephone: 7027800002 Fax: Email: frontdesk@heartsalivevillage.org

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable?		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable?		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

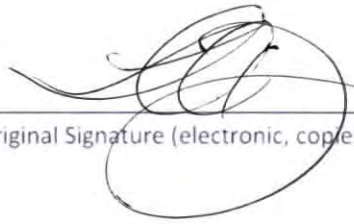
Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
March 2022	open	Nevada	Henderson	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
09-2019DVM-79		Nevada Veterinary Board		
Reason/Charge				
Record violation				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Nevada vet board/Terry Muratore			Arbitration	
Name of Business/Industry/Entity				
Legacy Animal Hospital				

Provide explanation below:

Board accusation of providing false rabies certificates to certain patients. In compliance to Nevada Administrative Code section 441A.435 paragraph 4 a practitioner may exempt a patient from vaccination based on examination or existing illness at the time that may contradict the administration of any biologics. My error was in not properly documenting the reason for the exemption on the certificate and as a result was accused of producing false rabies vaccination certificates. Current litigation is still pending. My license to practice is currently active status.



Original Signature (electronic, copies or stamps not accepted)

12/20/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered dispensing practitioner who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Terry Muratore

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/20/2023

Date

Board Use Only: Date Processed: _____ Amount: 150.00 CC

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BEFORE THE NEVADA STATE BOARD OF

BOARD OF VETERINARY MEDICAL EXAMINERS

IN THE MATTER OF: **TERRY MURATORE, D.V.M.,** **License No. 551-A,** **Respondent.**	**Case No. 03-2022DVM-10** **FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER**

This matter was heard by the Nevada State Board of Veterinary Medical Examiners on April 29 and May 14, 2022 in Las Vegas, Nevada. Board Staff was represented by Louis Ling, and Dr. Muratore was represented by Alan Westbrook of Perry & Westbrook. Based upon the evidence and testimony presented and the arguments of counsel, the Board finds the following to be the facts in this matter, makes conclusions about the applicable law, and orders as follows.

FINDINGS OF FACT

1. On March 8, 2022, Board Inspector Becky Phlegar performed a hospital inspection at LAH. In the course of the inspection, Ms. Phlegar found medical records made by Dr. Muratore that indicated that he had issued Certificates of Vaccination for animals to whom he had not administered a rabies vaccination.

2. Based upon Ms. Phlegar's findings, on March 11, 2022, the Board's President signed an Order of Summary Suspension of License to Practice Veterinary Medicine, the effect of which was the immediate suspension of Dr. Muratore's license to practice veterinary medicine.

3. On March 14, 2022, the Board's Executive Director, Jennifer Pedigo, served the Order of Summary Suspension on Dr. Muratore. Also on March 14, 15, and 16, Board Staff – Ms. Pedigo, Ms. Phlegar, and Dr. John Crumley, Board Investigator – investigated Dr. Muratore's rabies vaccination practices. Board Staff's investigation included copying a large number of medical files and interviewing LAH staff.

4. On March 25, 2022, Board Staff filed and served an Accusation and Notice of Hearing in the instant matter by which it charged Dr. Muratore with a cause of action regarding his rabies vaccination

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practices and by which it set a hearing for April 22, 2022. Pursuant to mutual agreement of the parties, the hearing was rescheduled for April 29, 2022.

5. On April 25, 2022, Dr. Muratore, through his counsel Alan W. Westbrook, filed a Response to Complaint.

6. A hearing was held on April 29, 2022 in Las Vegas, Nevada. At the hearing, Board Staff presented the testimony of Kevin Longoria, L.V.T., Chad Bower, D.V.M., John Crumley, D.V.M. Mr. Longoria, Dr. Bower, and Ms. Samuels all testified under compulsion of subpoena issued at the instance of Board Staff. Dr. Muratore presented the testimony of Dennis Nelson, Mary Jo Goodman, Donna Findlay, Nina Neely, Susan Sayegh, Christy Stevens, and Dr. Muratore. At the April 29, 2022 hearing, the parties stipulated to the entry into evidence of: (1) a packet of exhibits comprising 533 pages, and (2) a packet of statutes, regulations, ordinances, and a magazine article comprising 35 pages. The hearing was continued until May 14, 2022, at which Dr. Muratore completed his testimony and Board Staff presented the testimony of Heather Samuels as a rebuttal witness. At the May 14, 2022 hearing, the parties stipulated to the entry into evidence of: (1) the Compendium of Animal Rabies Prevention from JAVMA, Vol 248, No. 5, March 1, 2016 comprising 13 pages; and (2) "Annual rabies vaccination waiver" issued by the AVMA comprising one page.

7. At the time of the events in this matter, Dr. Muratore had been practicing veterinary medicine in Nevada for approximately 37 years, the last twelve at Legacy Animal Hospital (LAH), which he owned and for which he was the veterinarian in charge, though by the time of the hearing Dr. Muratore had sold LAH to Western Veterinary Partners. At the time of the events in this matter, Mr. Longoria was a licensed veterinary technician who had been licensed since 2002 and who had been working for Dr. Muratore and LAH since June 2019. At the time of the events in this matter, Dr. Bower was a veterinarian who had been licensed since 1997 and who had been working for Dr. Muratore and LAH since August 2020. At the time of the events in this matter, Ms. Samuels was a veterinary assistant employed at the front desk by Dr. Muratore and LAH for over five years.

8. Regarding Dr. Muratore's practices relating to the administration or non-administration of rabies vaccinations, Mr. Longoria and Dr. Bower both described that there were animals to whom Dr.

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Muratore would not administer a rabies vaccination but for which he would issue a Certificate of Vaccination on which he would indicate that he had, in fact, administered the rabies vaccination to the animal. Mr. Longoria said that he had been trained to prepare and draw up syringes for rabies vaccinations for veterinarians with whom he had previously worked, and also for Dr. Bower once he began working at LAH, and that when he had prepared the syringes, he would put the manufacturer's sticker on the syringe to identify the syringe as containing rabies vaccine and to assist in the ease of recordkeeping for the veterinarian. At LAH, Dr. Muratore deterred Mr. Longoria from preparing and drawing up syringes for vaccinations, including rabies vaccinations. Mr. Longoria also explained that when Dr. Muratore was going to see an animal for vaccinations, usually no other LAH personnel were present in the examination room, resulting in Dr. Muratore being alone with the animal and the client.

9. Dr. Bower stated that he was aware that Dr. Muratore was issuing Certificates of Vaccination for animals that he had not, in fact, vaccinated for rabies. As one of the ways in which he became aware of Dr. Muratore's rabies vaccination practices, Dr. Bower detailed a client encounter where a client had informed Dr. Bower that Dr. Muratore had not administered the rabies vaccine to her animal but had issued a Certificate of Vaccination anyways. Dr. Bower subsequently vaccinated that client's animal for rabies. Dr. Bower explained that he had several times had to explain to Dr. Muratore's clients that he, Dr. Bower, would vaccinate the client's animal because rabies vaccinations are legally mandated, and several times Dr. Bower would be seen by a client for a rabies vaccination for the client's animal after Dr. Muratore had not vaccinated the animal.

10. Ms. Samuels explained that she had been specifically instructed by Dr. Muratore to prepare and issue Certificates of Vaccination for animals that she knew had not been vaccinated, including issuing Certificates of Vaccination for animals and clients where the animals were not physically present at LAH and could not, therefore, have been vaccinated. The issuance of Certificates of Vaccination for animals who had not, in fact, been vaccinated was a regular occurrence at LAH and was always done with Dr. Muratore's knowledge and at his direction.

11. Dr. Crumley explained the methodology used by Board Staff in the course of its investigation. Dr. Crumley explained that Board Staff looked for certain markers in Dr. Muratore's

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medical files and billing records in cases where a Certificate of Vaccination had been issued by Dr. Muratore, including the lack of a manufacturer's sticker, the notation "3 yr. Rabies" or similar notation, and an indication in the medical record and/or the billing record that no charge had been assessed to the client for the rabies vaccination. Based upon a review of hundreds of medical files and billing records, Board Staff compiled a list of 143 medical files that bore evidence that Dr. Muratore had issued Certificates of Vaccination for animals that he had not, in fact, vaccinated for rabies. Of the 143 medical files identified, 36 medical files contained Certificates of Vaccination for animals who were not at LAH on the date that the rabies vaccination was supposedly administered by Dr. Muratore, and just under 100 medical files contained handwritten notations that a rabies vaccination had been administered by Dr. Muratore but did not contain a manufacturer's sticker for the vaccination supposedly administered, and 10 medical files contained indications that the animal was seen on the day that a Certificate of Vaccination was issued but there is no indication in the medical record that a rabies vaccination had been administered that same day.

12. Regarding the issue of exemptions from rabies vaccinations, Dr. Crumley testified that rabies vaccinations are mandatory by law, and, further, that the AVMA's position on exemptions from rabies vaccinations is that exemptions are only to made where the giving of the rabies vaccination would endanger the life of the animal. Dr. Crumley and Dr. Bower both explained that the only conditions for which an exemption would be appropriate would be for severe autoimmune diseases such as immune mediated hemolytic anemia or immune mediated thrombocytopenia. Dr. Crumley explained that an exemption would not be appropriate because of the animal's age, previous non-life-threatening reactions, pain at the injection site, gastrointestinal upset, of airborne or skin allergies as these could easily be treated prophylactically or with supportive aftercare and observation. Dr. Bower agreed that an animal's age would not be a reason for exemption from a rabies vaccination. In his 25-year veterinary career, Dr. Bower had never exempted an animal specifically from the rabies vaccination. In his 23-year career, Dr. Crumley had exempted fewer than five animals from the rabies vaccination, and all exemptions he gave were because the animals had severe autoimmune diseases. Dr. Crumley stated that in order to exempt an animal from rabies vaccination, the animal's condition

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and diagnosis would need to be recorded in the medical file and that the cause for the exemption would also need to be recorded in the medical file. Dr. Crumley stated that in none of the 143 records reviewed and made a part of the record of the hearing did the word "exemption" appear nor did any of the records contain an indication by Dr. Muratore that he had exempted any of the 143 animals from a rabies vaccination.

13. At hearing, Dr. Muratore presented the testimony of six of his clients: Dennis Nelson, Mary Jo Goodman, Donna Findlay, Nina Neely, Susan Sayegh, and Christy Stevens. The presentations included reviewing the medical files for the animals owned by each client. The testimonies of the clients proved problematic in view of the medical files for the various animals made by Dr. Muratore and Dr. Muratore's subsequent testimony. An analysis regarding each of Dr. Muratore's witnesses follows.

(a) Dennis Nelson: Mr. Nelson testified that he had been a client of Dr. Muratore's and a personal friend of Dr. Muratore's for over thirty years. At hearing, Mr. Nelson's testimony focused on his Chihuahua named Fabiana. Mr. Nelson regularly took Fabiana with him during his frequent visits to Mexico, so Mr. Nelson obtained both Certificates of Vaccination and USDA Certificates of Examination for Small Animals (USDA Certificates) from Dr. Muratore. The medical records for Fabiana contained two Certificates of Vaccination: in one Dr. Muratore certified having given Fabiana a rabies vaccination on March 20, 2017 and in another Dr. Muratore certified having given Fabiana a rabies vaccination on August 13, 2019. The two vaccination dates were contained in three USDA Certificates (3/20/17), one USDA Certificate (8/13/19), three Health Certificates to Export Dogs and Cats from the United States of America to Mexico (3/20/17), and one Certificate of Veterinary Inspection for Small Animals and Avian Species issued by the Nevada Division of Animal Industry (3/20/17). Dr. Muratore's medical records do not contain entries for either of the purported rabies vaccinations. Rather, regarding the purported rabies vaccination on March 20, 2017, Dr. Muratore's records show a patient encounter on November 21, 2016 and then a patient encounter on September 12, 2017 with no other patient encounters between those two dates. Dr. Muratore's records on August 13, 2019 show that Dr. Muratore saw Fabiana on that date, but that he only saw Fabiana for excessive

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urination for which he prescribed Clindamycin liquid and that Dr. Muratore did not administer a rabies vaccination (or any other vaccination) to Fabiana on that day. Under cross-examination, Dr. Muratore could not prove from his medical records either of Fabiana's rabies vaccinations; instead, Dr. Muratore relied upon his memory of events five and three years earlier in combination with the issuance of the Certificates of Vaccination themselves. Based upon the reliable evidence, it appears that Fabiana was not, in fact, vaccinated for rabies and that the two Certificates of Vaccination and the eight USDA Certificates needed so that Fabiana could be taken by Mr. Nelson to Mexico were false.

(b) Mary Jo Goodman: Ms. Goodman explained that she was employed by an unidentified couple for fifteen years, during which she was responsible for the couple's dogs, including taking the dogs to Dr. Muratore. At hearing, Ms. Goodman testified about one of the dogs, a goldendoodle named Teddy, who was a therapy dog who was taken to libraries to interact with children. Ms. Goodman also testified regarding a second of her employer's dogs named Jerry. On cross-examination, Ms. Goodman testified that maintaining the dogs was one of her job duties for the unidentified couple and that it was important to her, in maintaining the dogs for her unidentified employers, that the dogs be properly vaccinated. Despite her profession of desiring that the dogs be properly vaccinated, the medical records for Jerry show that he was only vaccinated every six years instead of the legally mandated every three years. Ms. Goodman offered no plausible explanation for why Jerry had not been timely vaccinated for rabies, but she did state that Dr. Muratore had not reminded her of Jerry's rabies vaccination status. The medical records for Jerry did not contain records regarding an encounter on June 8, 2020 during which Dr. Muratore purportedly vaccinated Jerry for rabies according to a Certificate of Vaccination issued for Jerry on June 8, 2020, and Ms. Goodman had no recollection of the encounter or whether Jerry had, in fact, received a rabies vaccination. Regarding Teddy, the service dog who interacted with children, the Certificate of Vaccination showed that Teddy received his first puppy rabies vaccination, which was a one-year vaccination, on May 29, 2014 and that he did not receive another rabies vaccination until October 14, 2020, meaning that Teddy did not receive his first booster that should have been administered in May 2015 and that he, in fact, had not been vaccinated for six and one-half years. Ms. Goodman offered no plausible explanation for why Teddy had not been vaccinated for over

six years. Under questioning from a Board member, Ms. Goodman offered no plausible explanation for how Teddy was exposed to giardia, but that in being treated for giardia, it demonstrated that Teddy was exposed to the natural elements since that is how giardia is contracted. Dr. Muratore's medical records regarding Teddy shows an encounter on October 14, 2020, but the records do not include a manufacturer's sticker for the purported rabies vaccine administered that day. Therefore, Dr. Muratore's records do not support and cannot prove that either Jerry or Teddy was vaccinated for rabies and demonstrate a disregard by Dr. Muratore and Ms. Goodman for the legal mandate that both dogs be vaccinated for rabies at all times, including boosters every three years. As with Mr. Nelson, Dr. Muratore's medical records are troubling in view of the salutary public policy supporting the maintenance of every dog's rabies vaccination status, regardless of whether the owners live in a gated community.

(c) Nina Neely: Ms. Neely stated that she had been a client of Dr. Muratore's for four years and that he treated her three Cavalier King Charles Spaniels. Ms. Neely's testimony focused on one of the three dogs named Rhianna. Ms. Neely testified that Dr. Muratore did not vaccinate Rhianna for rabies on June 10, 2021 because Rhianna on that day Rhianna was brought in for cancer surgery and that Rhianna had mitral valve disease. Ms. Neely also testified that despite Dr. Muratore not administering a rabies vaccination, she left his office that day with a Certificate of Vaccination by which Dr. Muratore indicated that he had, in fact, vaccinated Rhianna for rabies that day. Ms. Neely also acknowledged that on June 10, 2021 Dr. Muratore also issued a Certificate of Vaccination for Onyx, another of Ms. Neely's dogs, even though Onyx had not seen or been treated by Dr. Muratore that day. On cross-examination, Ms. Neely conceded that on June 10, 2021, Rhianna was not being seen by Dr. Muratore for a cancer treatment but, instead, was being seen for a lumpectomy, meaning that on June 10, 2021 there was no diagnosis of cancer because the lumpectomy had not even yet been performed. Furthermore, Ms. Neely conceded that Rhianna's Certificate of Vaccination resultant from the visit on June 10, 2021 was false because Rhianna had not, in fact, been vaccinated for rabies, as was also indicated in Dr. Muratore's medical records. Ms. Neely further conceded that when Rhianna's records were sent by LAH to a veterinary facility in Santa Cruz, California, the records that would have been

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sent would have indicated that Rhianna had been vaccinated for rabies when, in fact, she had not. Dr. Muratore testified that the cause for exemption for Rhianna was that she had been diagnosed with a cancerous growth that would best respond to irradiation therapy. Unfortunately, this representation is untrue because Dr. Muratore's records show that on June 10, 2021, Rhianna was being seen for a lumpectomy, which is a procedure that precedes any diagnosis of a lump, meaning that Rhianna was not, in fact, diagnosed with cancer on June 10, 2021. Dr. Muratore also testified that on June 10, 2021, Rhianna was on immunosuppressant drugs, but Dr. Muratore's records do not indicate any diagnosis of cancer on, prior to, or after June 10, 2021, and the only prescription indicated in Dr. Muratore's medical records for Rhianna was pimobendan, which is a drug for congestive heart failure and is not an immunosuppressant. Dr. Muratore further indicated that his medical records for Rhianna did not indicate that he had exempted Rhianna from a rabies vaccination, much less that there was a valid medical cause to do so. Based upon Dr. Muratore's and Ms. Neely's testimony and Dr. Muratore's own records, the records do not support that there was cause to exempt Rhianna on June 10, 2021 from a rabies vaccination and, therefore, that the two Certificates of Vaccination issued on June 10, 2021 (Rhianna and Onyx) and the Certificates of Vaccination were and are false. This is particularly troubling where the false records were then provided by LAH to a veterinary facility in Santa Cruz, California and where, on their face, the records falsely indicate that Rhianna had been vaccinated for rabies when, in fact, she had not.

(d) Susan Sayegh: Ms. Sayegh was a client of Dr. Muratore's for nine years and he has treated her dogs, including Ricky, the focus of her testimony. Regarding Ricky, Ms. Sayegh testified that Dr. Muratore temporarily exempted Ricky from his due rabies vaccination because Ricky was experiencing diarrhea at the time, and she recalled receiving antibiotics to address the diarrhea. She also remembered that Dr. Muratore gave her a Certificate of Vaccination despite Dr. Muratore not having vaccinated Ricky for rabies. Dr. Muratore's records were directly contrary to Ms. Sayegh's testimony. Dr. Muratore's medical records for February 25, 2022 show her concern with diarrhea for which he was taking no medications, but Dr. Muratore's own handwritten notes indicate, instead, that Ricky was having two bowel movements a day, which would be normal. The medical records document Ms.

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Sayegh's concern with a growth on Ricky's head, and the medical records in Dr. Muratore's showed "3yr Rabies." The Certificate of Vaccination shows a rabies vaccination was administered on February 25, 2022 and that if that rabies vaccine had, in fact, been administered (which Ms. Sayegh denied), it would have been the first such rabies vaccination in at least seven years. On cross-examination, Ms. Sayegh conceded that Dr. Muratore's medical records and the Certificate of Vaccination were false because no rabies vaccination had been administered on February 25, 2022. More distressing, though, was Ms. Sayegh's testimony that Ricky had gotten into a bloody fight with a dog she was fostering, that she took both dogs to another veterinary facility for emergency treatment, and that at that veterinary facility she did not inform the treating veterinarian that Ricky had not had a rabies vaccination in at least the past seven years. This meant that the veterinarian treating Ricky for the dog fight injuries had no way to know about Ricky's longtime unvaccinated status, and, therefore, had no way to protect himself, his staff, and the other animals in the facilities from a longtime unvaccinated dog who was bleeding at the veterinary facility. On cross-examination, Dr. Muratore testified that he had not administered a rabies vaccination to Ricky on February 25, 2022, and that his handwritten notation "3yr Rabies" was intended to signal that he had ***not*** given the rabies vaccination. Additionally, contrary to Dr. Muratore's testimony that he had been treating Ricky for diarrhea, Dr. Muratore's medical records show that Ricky was not on any medications for his diarrhea. Thus, Dr. Muratore's own presentation proved: (a) that he had a dog under his care for nine years that was allowed to go at least seven years without being vaccinated for rabies; (b) that Dr. Muratore's records were proven false by his own testimony and the testimony of his witness; (c) that Dr. Muratore's longtime unvaccinated patient was taken to another veterinary facility bleeding from a dog fight under circumstances where the treating veterinarian and facility had not way to know that their emergency patient was longtime unvaccinated; and (4) that had the treating veterinarian checked Ricky's medical records, he would have concluded that Ricky was vaccinated when, in fact, he was not. Under examination by his counsel, Dr. Muratore explained that in his medical records there are sometimes manufacturer's stickers for rabies vaccinations and that sometimes there are no stickers for rabies vaccinations because the stickers get torn, fall off, get lost, or are given to the clients. These explanations regarding the stickers appear

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untrue or implausible and exhibit a troubling and cavalier attitude regarding rabies vaccinations which are mandatory for salutary public policy reasons.

14. Dr. Muratore's records were entirely unreliable as evidence of what rabies vaccinations he did or did not administer. For example, Dr. Muratore testified that his handwritten notation "3yr Rabies" meant that he had administered the vaccination sometimes and that he had not administered the vaccination at other times, rendering such notations throughout the 143 medical records meaningless. Both Dr. Muratore and many of his witnesses conceded that Dr. Muratore's records were false. The patient records of Dr. Muratore's witnesses ran the gamut of concerns noted by Dr. Crumley during his testimony: Mr. Nelson (Fabiana) and Ms. Goodman (Jerry) received Certificates of Vaccination (and Fabiana multiple international certificates of health) for dates on which the dogs were not even at LAH, Ms. Sayegh (Ricky) was an example of a medical record showing a rabies vaccination with no corresponding manufacturer's sticker, and Ms. Neely (Rhianna) was an example of a date on which a patient was seen by Dr. Muratore and a Certificate of Vaccination was issued where there is no indication in the medical record that a rabies vaccination was administered. Dr. Muratore testified extensively about granting exemptions from rabies vaccinations to his patients for "health reasons," but he also admitted he did not know about the regulation allowing for such exemptions until this disciplinary action was initiated and there is not a single word in any of the 143 records examined in this matter about him considering or granting an exemption for any of the 143 patients at issue. Dr. Muratore testified at length about contradictory and unsubstantiated scientific claims related to rabies vaccinations where such understanding and knowledge is irrelevant because the law enjoins on all of Nevada's veterinarians the duty to actively participate in the protection of the public by mandatorily giving rabies vaccinations to all dogs, cats, and ferrets.

15. Taken as a whole, the presentations of the parties amply demonstrated that Dr. Muratore routinely issued Certificates of Vaccination for animals that he had not, in fact, vaccinated for rabies. Dr. Muratore's medical records were replete with false representations indicating the administration of rabies vaccinations when he had not administered such. Each Certificate of Vaccination issued by Dr. Muratore where he had not, in fact, administered the rabies vaccine is also false. Dr. Muratore's

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explanations about when and why he would 'exempt' an animal from the rabies vaccine varied situationally, were not borne out in the medical records he made, were at variance with the actual contents of the records he made and were not grounded in extant medical standards such as were provided by the AVMA. Dr. Muratore's practice regarding rabies vaccination demonstrates, overall, a disconcerting lack of knowledge, skill, or care regarding the critical part Nevada's veterinarians play in protecting the public and its animals from rabies through the routine and mandatory vaccination of virtually all animals brought to them.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter because at all times pertinent to this matter Dr. Muratore was a veterinarian licensed by the Board (License No. 551-A).

2. In the Accusation in this matter, Dr. Muratore was charged with violations of Nevada Revised Statutes (NRS) 628.140(1) and/or NRS 638.140(8) and/or NRS 638.1402(4) and/or NRS 638.1408(4) and/or Nevada Administrative Code (NAC) 638.048(1) and/or NAC 638.048(2) and/or NAC 638.048(4). Furthermore, the Accusation made it patent that each failure to vaccinate an animal and each certification of having done so constitutes a separate violation of the statutes and regulations cited within this paragraph and, therefore, constitutes a separate and distinct cause for discipline.

3. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NRS 638.140(1) by violating regulations adopted by the Board as will be detailed in subsequent paragraphs.

4. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NRS 638.140(8) by willfully vailing to comply with the standard of care established by the American Veterinary Medical Association (AVMA). In particular, Dr. Muratore's descriptions of why and how he exempted animals from the rabies vaccination were not in conformance with the JAVMA's Compendium of Animal Rabies Prevention and Control, 2016 and the AVMA Policy entitled Annual rabies vaccination waiver, both of which were received into evidence at the hearing.

5. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NRS 638.1402(4) in that Dr. Muratore's practice of issuing Certificates of Vaccination where he knew

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that he had not, in fact, vaccinated the animals was conduct likely to deceive recipients of those certificates and was conduct likely to harm the public because Dr. Muratore was disseminating information concerning his services – namely the administration of rabies vaccinations – which was false and which he knew to be false at the time that he issued the certificates.

6. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NRS 638.1408(4) in that Dr. Muratore made reports, namely Certificates of Vaccination and international certificates of health, certifying that he had administered rabies vaccinations to animals that he knew he had not, in fact, vaccinated, and in so certifying, all of these certificates were false.

7. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NAC 638.048(1) in that he falsified records of health care every time he indicated in his medical records that he had vaccinated an animal for rabies where he had not, in fact, done so and every time he certified on a Certificate of Vaccination or USDA Certificate that he had vaccinated an animal for rabies when, in fact, he had not.

8. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NAC 638.048(2) in that he indicated in his medical records and in Certificates of Vaccination and USDA Certificates that he had performed procedures, namely the administration of rabies vaccinations to animals, that he had not, in fact, performed.

9. The substantial, reliable, and credible evidence at hearing proved that Dr. Muratore violated NAC 638.048(4) in that his consistent practice of not administering rabies vaccines to animals in his care and then indicating in his medical records and subsequent Certificates of Vaccination and international health certificates for those animal in which he certified that he had done what he had, in fact, not done was a serious departure from the prevailing standards of acceptable veterinary medical practice.

10. The substantial, reliable, and credible evidence at hearing compels the conclusion that Dr. Muratore made a regular practice of not administering rabies vaccinations to animals in his care and then indicating in his medical records and certifying in official documents that he had, in fact, administered the rabies vaccination. This conduct is deeply troubling for two reasons. First, the

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statutes, regulations, and ordinances reviewed at the hearing indicate that the Nevada Legislature, the State Department of Health, and the governing boards of the various local jurisdictions as well as the AVMA Compendium that is incorporated by reference into these laws all hinge Nevada's rabies control and prevention efforts upon an implicit trust in the reliability and veracity of Nevada's veterinarians. Dr. Muratore repeatedly and regularly betrayed this public trust. Second, the Board, patients, public agencies, international agencies, and fellow veterinarians must be able to depend upon and trust the veracity of Dr. Muratore's medical records and certifications because important decisions relating to the patients under Dr. Muratore's care will be made based upon his medical records. Dr. Muratore repeatedly and regularly betrayed this trust and duty of a veterinarian by making false medical records and certificates indicating he had administered rabies vaccinations to animals that he had not, in fact, vaccinated. We conclude that these violations of trust by Dr. Muratore were intentional, willful, and, therefore, of the highest concern as to his reliability, credibility, and veracity.

ORDER

Based upon the above findings of fact and conclusions of law, the Board hereby orders the following:

1. Dr. Muratore's license (License No. 551-A) is suspended for 18 months commencing on March 14, 2022. During this period of suspension, the following terms and conditions will apply:

(a) With the sole exception of his own personal animals, Dr. Muratore may not perform any act upon an animal in Nevada for which licensure would be required or that would otherwise constitute the practice of veterinary medicine. During this period of suspension, Dr. Muratore may not be in any veterinary facility except in the context of being the owner of an animal in need of care.

(b) Board Staff shall obtain from LAH a list of all clients and animals for which the records show that Dr. Muratore administered a rabies vaccination for the period of March 14, 2018 to present. Board Staff shall provide a copy of the list to Dr. Muratore. Within 15 days of having been provided a copy of the list, Dr. Muratore shall notify each client regarding each animal on the list that the animal may not have received a rabies vaccination and that each client is instructed that if the client has not received a rabies vaccination from another veterinarian since the one shown for Dr. Muratore the client

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should immediately take his or her animal(s) to another veterinarian to receive a rabies vaccination. Before Dr. Muratore mails or e-mails the notification, he shall provide his intended text to Board Staff and shall not mail or e-mail the text to the clients until he and Board Staff have reached agreement as to the text. Dr. Muratore shall mail or e-mail each client at his own cost, and shall notify Board Staff the date on which he has done so.

(c) During the period of suspension, Dr. Muratore shall pay the Board's fees and costs totaling $54,216.43 by check, money order, credit card, or certified or cashier's check made payable to "Nevada State Board of Veterinary Medical Examiners." The fees and costs ordered in this paragraph must be received by the Board office no later than September 30, 2022.

(d) During the period of suspension, Dr. Muratore shall pay a fine of $36,000.00 ($1,000 for each of the 36 animals for whom he issued Certificates of Vaccination on days on which the animals were not at LAH) by check, money order, credit card, or certified or cashier's check made payable to "Nevada State Board of Veterinary Medical Examiners." The fine ordered in this paragraph must be received by the Board office by the end of the suspension period.

(e) Dr. Muratore's suspension will continue if: (1) Dr. Muratore has not cooperated and assisted with the notification of the clients; (2) Dr. Muratore has not paid all the costs related to the forensic document review ordered in subparagraph 1(b); (3) Dr. Muratore has not paid timely the fees and costs ordered in subparagraph 1(c); or (d) Dr. Muratore has not paid the fine ordered in subparagraph 1(d).

(f) If Dr. Muratore breaches any of the terms or conditions of his suspension above, Board Staff shall commence disciplinary action seeking the revocation of Dr. Muratore's license thereby. If Dr. Muratore's license is thereby revoked, all monies ordered or due and owing as a result of subparagraphs 1(b) – 1(d) above shall immediately become due and owing.

2. After the period of suspension terminates, Dr. Muratore's license shall be on probation for a period of one year. The terms and conditions of the probations shall be:

(a) Dr. Muratore shall shadow one or more general practice veterinarians in their practices for 80 hours. The Board's office shall submit to Dr. Muratore the name or names of veterinarians with whom he could shadow, and Dr. Muratore shall notify the Board's Executive Director with which

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veterinarians he will shadow. The shadowing veterinarian or veterinarians shall provide to the Board's office an accounting for the days and times at which Dr. Muratore shadowed with them. The intent of the shadowing under this subparagraph is to have Dr. Muratore relearn and understand how other general practice veterinarians handle day-to-day tasks, including vaccinations, and how they make medical records related thereto.

(b) Dr. Muratore shall bear and pay all costs associate with the shadowing ordered herein.

(c) The period of probation shall continue beyond one year until Dr. Muratore completes fully and successfully the terms of probation. If Dr. Muratore fails to complete fully and successfully any of the terms of probation for more than six months after the probation was otherwise due to terminate, Dr. Muratore's license will immediately thereafter be revoked upon written notification of the Board's Executive Director and without further action by the Board.

(d) After Dr. Muratore has successfully and fully completed the terms and conditions of probation, this matter will be placed upon the Agenda of the next regularly scheduled Board meeting at which Dr. Muratore will appear before the Board so the Board can ask pertinent questions and obtain pertinent information and documents regarding Dr. Muratore's return to practice, and if the Board finds that Dr. Muratore can safely and ethically return to practice, the Board shall terminate the probation and this Order.

3. Dr. Muratore shall take and successfully complete 80 hours of continuing education related to medical ethics, medical recordkeeping, and rabies prevention and exemptions in small animals. The 80 hours of continuing education in this subparagraph must be completed by the end of the period of probation and cannot count as part of the continuing education obligation to renew his license.

4. Dr. Muratore shall meet with, cooperate with, and allow the review of any and all records related to his practice of veterinary medicine throughout the period of suspension and the period of probation. Failure to so cooperate will result in Board Staff's pursuing disciplinary action to revoke Dr. Muratore's license.

ORDERED AND EFFECTIVE this _____ day of July 21, 2022.

MICHAEL KNEHR, D.V.M., Board Member

MELISSA SCHALLES, L.V.T., Board Member

JOHN BULLARD, D.V.M., Board Member

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CERTIFICATE OF SERVICE

I certify that on this day I served via U.S. Mail postage prepaid a true and correct copy of the foregoing document addressed to the following:

LOUIS LING
[redacted] GEAR STREET
RENO, NEVADA 89503

ALAN WESTBROOK
PERRY & WESTBROOK
1701 W. CHARLESTON BLVD., SUITE 200
LAS VEGAS, NEVADA 89102

and via e-mail addressed to: louisling@me.com and awestbrook@perrywestbrook.com .

Dated this 24 day of August, 2022.

EMPLOYEE OF THE BOARD

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BEFORE THE NEVADA STATE BOARD OF

BOARD OF VETERINARY MEDICAL EXAMINERS

IN THE MATTER OF: **TERRY MURATORE, D.V.M.,** **License No. 551-A,** **Respondent.**	**Case No. 03-2022DVM-10** **JOINT STIPULATION AND ORDER RE: RESPONDENT'S PETITION FOR RECONSIDERATION**

BACKGROUND FOR JOINT STIPULATION

This matter was heard by the Nevada State Board of Veterinary Medical Examiners on April 29 and May 14, 2022 in Las Vegas, Nevada. Board Staff was represented by Louis Ling, and Dr. Muratore was represented by Alan Westbrook of Perry & Westbrook.

On August 24, 2022, the hearing panel of the Board issued its Findings of Fact, Conclusions of Law, and Order (the Order), which was subsequently served by mail on the parties on August 31, 2022.

On September 8, 2022, Dr. Muratore filed a Petition for Reconsideration. By the Petition, Dr. Muratore sought the hearing panel's reconsideration of various portions of the discipline imposed in the Order, mostly on the basis that the Order caused certain negative financial impacts that were unknown to the hearing panel at the time that it imposed the Order.

Subsequent to September 8, 2022, Board Staff and Dr. Muratore engaged in discussions and negotiations in an attempt to address and resolve the concerns with the Order raised in the Petition and to avoid further legal proceedings in the matter. The parties reached certain agreements and understandings that would modify some provisions of the Order as set out herein. The parties now ask the hearing panel for its consideration, and if it is the will of the panel, its modification of the Order as set out below.

JOINT PROPOSED AMENDMENT OF ORDER

The entirety of the "Discipline" section of the Order is set out below shall be amended as follows as noted in yellow highlighting:

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1. Dr. Muratore's license (License No. 551-A) is suspended for ~~18~~ 12 months commencing on March 14, 2022. During this period of suspension, the following terms and conditions will apply:

(a) With the sole exception of his own personal animals or as otherwise allowed in subparagraph (aa) following, Dr. Muratore may not perform any act upon an animal in Nevada for which licensure would be required or that would otherwise constitute the practice of veterinary medicine. During this period of suspension, Dr. Muratore may not be in any veterinary facility except in the context of being the owner of an animal in need of care.

(aa) If Dr. Muratore opts to perform 360 hours of volunteer work pursuant to subparagraph (1)(d) below, he shall so notify the Board office. Though the parties intend that Dr. Muratore will complete the 360 hours during the period of suspension, if that cannot be accomplished Dr. Muratore will so notify the Board office. In order to do so, Dr. Muratore must inform Board Staff of the non-profit facility at which he will be providing volunteer services before commencing any such volunteer work, and he may not commence any such work until he has received approval from Board Staff. During such volunteer work, Dr. Muratore may not be the only veterinarian on duty at any time while he is providing volunteer services. During such volunteer work, Dr. Muratore could not exempt any animal from rabies vaccination, and if he identified an animal for whom he believed an exemption was necessary and proper, he would refer the animal to another veterinarian for his or her assessment. The referred veterinarian would make a determination to vaccinate or to exempt from vaccination the animal referred by Dr. Muratore independently of Dr. Muratore. Before performing any volunteer work, Dr. Muratore would provide a current certificate of malpractice insurance if malpractice insurance can be obtained during a period of suspension. If Dr. Muratore cannot obtain malpractice insurance during a period of suspension, he shall so notify the Board office and any non-profit facility at which he intends to work. Dr. Muratore will obtain from the non-profit facility a document accounting for the dates, times, and work performed for that non-profit facility, which certificate Dr. Muratore would then provide to Board Staff.

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(b) Board Staff shall obtain from LAH a list of all clients and animals for which the records show that Dr. Muratore administered a rabies vaccination for the period of March 14, 2018 to present. Board Staff shall provide a copy of the list to Dr. Muratore. Within 15 days of having been provided a copy of the list, Dr. Muratore shall notify each client regarding each animal on the list that the animal may not have received a rabies vaccination and that each client is instructed that if the client has not received a rabies vaccination from another veterinarian since the one shown for Dr. Muratore the client should immediately take his or her animal(s) to another veterinarian to receive a rabies vaccination. Before Dr. Muratore mails or e-mails the notification, he shall provide his intended text to Board Staff and shall not mail or e-mail the text to the clients until he and Board Staff have reached agreement as to the text. Dr. Muratore shall mail or e-mail each client at his own cost, and shall notify Board Staff the date on which he has done so.

(c) ~~During the period of suspension, Dr. Muratore shall pay the Board's fees and costs totaling $54,216.43 by check, money order, credit card, or certified or cashier's check made payable to "Nevada State Board of Veterinary Medical Examiners." The fees and costs ordered in this paragraph must be received by the Board office no later than September 30, 2022.~~

(d) During the period of suspension, Dr. Muratore shall either: (1) pay a fine of $36,000.00 ($1,000 for each of the 36 animals for whom he issued Certificates of Vaccination on days on which the animals were not at LAH) by check, money order, credit card, or certified or cashier's check made payable to "Nevada State Board of Veterinary Medical Examiners"; or (2) perform 360 hours of volunteer services for a non-profit veterinary facility pursuant to the terms and conditions in subparagraph (aa) above. The fine ordered in this paragraph must be received by the Board office by the end of the suspension period.

(e) Dr. Muratore's suspension will continue if: (1) Dr. Muratore has not cooperated and assisted with the notification of the clients~~; (2) Dr. Muratore has not paid all the costs related to the forensic document review ordered in subparagraph 1(b); (3) Dr. Muratore has not paid timely the fees and costs ordered in subparagraph 1(c); or (d)~~ or if Dr. Muratore has opted to pay

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the fine rather than perform the 360 volunteer hours, Dr. Muratore has not paid the fine ordered in subparagraph 1(d).

(f) If Dr. Muratore breaches any of the terms or conditions of his suspension above, Board Staff shall commence disciplinary action seeking the revocation of Dr. Muratore's license thereby. If Dr. Muratore's license is thereby revoked, all monies ordered or due and owing ~~as a result of subparagraphs 1(b) – 1(d) above~~ shall immediately become due and owing.

2. After the period of suspension terminates, Dr. Muratore's license shall be on probation for a period of ~~one year~~ three years. The terms and conditions of the probations shall be:

(a) Dr. Muratore shall shadow one or more general practice veterinarians in their practices for 80 hours. The Board's office shall submit to Dr. Muratore the name or names of veterinarians with whom he could shadow, and Dr. Muratore shall notify the Board's Executive Director with which veterinarians he will shadow. A veterinarian with whom Dr. Muratore could shadow could be a veterinarian at a veterinary facility at which Dr. Muratore was employed or working. The shadowing veterinarian or veterinarians shall provide to the Board's office an accounting for the days and times at which Dr. Muratore shadowed with them. The intent of the shadowing under this subparagraph is to have Dr. Muratore relearn and understand how other general practice veterinarians handle day-to-day tasks, including vaccinations, and how they make medical records related thereto.

(aa) When Dr. Muratore commences working as a veterinarian during the period of probation, Dr. Muratore's work as a veterinarian shall be subject to the following terms and conditions: (1) Dr. Muratore may not be the only veterinarian on duty at any time while he is providing volunteer services; (2) Dr. Muratore could not exempt any animal from rabies vaccination, and if he identified an animal for whom he believed an exemption was necessary and proper, he would refer the animal to another veterinarian for his or her assessment, and the referred veterinarian would make a determination to vaccinate or to exempt from vaccination the animal referred by Dr. Muratore independently of Dr. Muratore; (3) Dr. Muratore would

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provide a current certificate of malpractice insurance to Board Staff when he commences work and within one week after each annual renewal thereof; (4) Dr. Muratore would provide to Board Staff on a quarterly basis a list of all veterinary facilities at which he worked as a veterinarian for the preceding quarter, including a listing of dates and shifts at which he was employed at each facility.

(aaa) If Dr. Muratore is otherwise in compliance with all the terms of probation set out herein, at the end of eighteen full months of probation he may petition the hearing panel to terminate subparagraph (aa)(1) and, if the hearing panel so allows, thereafter he may work in a veterinary facility as the only veterinarian on duty throughout the remainder of the probationary period.

(b) Dr. Muratore shall bear and pay all costs associate with the shadowing ordered herein.

(bb) Dr. Muratore shall pay the Board's fees and costs totaling $54,216.43 by check, money order, credit card, or certified or cashier's check made payable to "Nevada State Board of Veterinary Medical Examiners." The fees and costs ordered in this paragraph shall be paid in 11 installments of $4,500.00 and a final installment of $4,716.43, all to be received by the Board office no later than the last day of each quarter after the first payment, which is due on March 30, 2023.

(c) The period of probation shall continue beyond ~~one year~~ three years until Dr. Muratore completes fully and successfully the terms of probation. If Dr. Muratore fails to complete fully and successfully any of the terms of probation for more than six months after the probation was otherwise due to terminate, Dr. Muratore's license will immediately thereafter be revoked upon written notification of the Board's Executive Director and without further action by the Board.

(d) After Dr. Muratore has successfully and fully completed the terms and conditions of probation, this matter will be placed upon the Agenda of the next regularly scheduled Board meeting at which Dr. Muratore will appear before the Board so the Board can ask pertinent

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questions and obtain pertinent information and documents regarding Dr. Muratore's return to practice, and if the Board finds that Dr. Muratore can safely and ethically return to practice, the Board shall terminate the probation and this Order.

~~3.~~ (e) Dr. Muratore shall take and successfully complete 80 hours of continuing education related to medical ethics, medical recordkeeping, and rabies prevention and exemptions in small animals. The 80 hours of continuing education in this subparagraph must be completed by the end of the period of probation and cannot count as part of the continuing education obligation to renew his license.

~~4.~~ 3. Dr. Muratore shall meet with, cooperate with, and allow the review of any and all records related to his practice of veterinary medicine throughout the period of suspension and the period of probation. Failure to so cooperate will result in Board Staff's pursuing disciplinary action to revoke Dr. Muratore's license.

The parties further stipulate that this Joint Stipulation will be presented to the hearing panel of Board at its special meeting on September 29, 2022 and that if the hearing panel of the Board agrees to this Stipulation and Order, Dr. Muratore will thereafter waive his right to seek judicial review of the Order.

Signed this 26th day of September, 2022.

NEVADA STATE BOARD OF VETERINARY MEDICAL EXAMINERS

By: _____
Louis Ling, Board Counsel
Counsel for Board Staff

RESPONDENT DR. TERRY MURATORE

By: _____
Alan Westbrook
Perry & Westbrook
Counsel for Dr. Terry Muratore

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ORDER

THIS MATTER having come before the hearing panel in the above matter at a special meeting on September 29, 2022, and the hearing panel having considered the above Joint Stipulation and Order re: Respondent's Petition for Reconsideration, and having heard argument in support thereof from the parties, and good cause appearing

IT IS HEREBY ORDERED that the Joint Stipulation and Order re: Respondent's Petition for Reconsideration is approved and herein ordered as set out therein and those portions of the hearing panel's Findings of Fact, Conclusions of Law, and Order issued on August 24, 2022 shall be modified as set out in the Joint Stipulation.

ORDERED AND EFFECTIVE this 20 day of October, 2022.

MICHAEL KNEHR, D.V.M., Board Member

JOHN BULLARD, D.V.M., Board Member

CERTIFICATE OF SERVICE

I certify that on this day I served via U.S. Mail postage prepaid a true and correct copy of the foregoing document addressed to the following:

LOUIS LING
[redacted] GEAR STREET
RENO, NEVADA 89503

ALAN WESTBROOK
PERRY & WESTBROOK
1701 W. CHARLESTON BLVD., SUITE 200
LAS VEGAS, NEVADA 89102

and via e-mail addressed to: louisling@me.com and awestbrook@perrywestbrook.com .

Dated this 3 day of ~~October~~ NOVEMBER, 2022.

EMPLOYEE OF THE BOARD

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ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – January 2024			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
SC engaged in unprofessional conduct by an APRN when she sold/dispensed dangerous drugs without having obtained a certificate of registration.	N/A	Fined $5,000; assessed $500 in recoverable attorney's fees and costs.	N/A
TH overrode a DUR alert signaling a drug-interaction with another prescription. The prescription was misfilled and provided to the incorrect patient. MW failed to provide counseling or properly counsel patient's mother.	N/A	TH and MW each fined $1,000; assessed $350 in recoverable attorney's fees and costs.	Fined $2,000; assessed $350 in recoverable attorney's fees and costs.
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employees where the patient was given clonazepam 0.5mg instead of ibuprofen and amoxicillin which resulted in patient harm.	Yes	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
MO issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances while travelling out of country. MO participated in deceitful transactions and billed Medicaid for services that respondent did not provide.	N/A	Certificate of Registration No. CS10935 is revoked. MO cannot reapply for a period of ten years. Fined $2,500; assessed $1,754.68 in recoverable attorney's fees and costs.	N/A
PR assisted in unauthorized prescribing when she allowed her medical assistant to use her signature stamp for controlled substance prescriptions.	N/A	Fined $1,500; assessed $500 in recoverable attorney's fees and costs.	N/A
CVS, as pharmacy/pharmacy owner, is responsible for the dispensing errors of its employee who erroneously dispensed Estradoil 0.5mg and failed to counsel the patient	Yes	N/A	Fined $3,000.00; assessed $2,000.00 in recoverable attorney's fees and costs.

ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – January 2024			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
which resulted in patient harm.			
JC, as managing pharmacist, is responsible for the dispensing errors of employees that failed to dispense Doxycycline 50mg simultaneously with another prescription Metronidazole 250mg which were supposed to be taken as the prescribed course of treatment.	N/A	Respondent fined $1,000.00; assessed $500.00 in recoverable attorney's fees and costs	Fined $2,000; assessed $1,000 in recoverable attorney's fees and costs.
CD Rx failed to properly disclose that they had pending administrative actions in Alabama and Louisiana Boards of Pharmacy on their 2020 business renewal application.	N/A	N/A	Fined $1,000; assessed $500 in recoverable attorney's fees and costs.
EA failed to comply with the citation and fine dated June 30, 2023, due to his failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. EA was sent an Order to Show Cause on November 29, 2023, which he failed to appear, and a default was made. Respondent's Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A	Certificate of Registration No. 19224 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A
JI failed to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. JI was sent an Order to Show Cause on November 29, 2023, which she failed to	N/A	Certificate of Registration No. 09672 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	N/A

ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – January 2024			
FINDING	HARM	DISCIPLINE INDIVIDUAL	DISCIPLINE FACILITY
appear, and a default was made.			
OE failed to comply with the citation and fine dated June 30, 2023, due to her failure to complete the thirty CE credits required by NAC 639.330 for their pharmacist biennial registration period for November 1, 2019, to October 31, 2021. OE sent an Order to Show Cause on November 29, 2023, which she failed to appear, and a default was made.		Certificate of Registration No. 16558 is revoked and cannot reapply for a period of one year; assessed $506.67 in recoverable attorney's fees and costs.	

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FILED
NOV 16 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9967,** **Pharmacy License No. PH01250, and** **MIHRETEAB TESEMA, RPH,** **Certificate of Registration No. 18570,** **Respondents.**	**CASE NOS. 19-049-PH-S** **19-049-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Mihreteab Tesema, RPH (Tesema), Certificate of Registration No. 18570, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9967, Pharmacy License No. PH01250, was a pharmacy licensed by the Board.

2. By Board order entered January 10, 2018, in Case No. 17-032-RPH-S, Tesema stipulated to discipline including a public reprimand and a fine for prescription dispensing errors.

FACTUAL ALLEGATIONS

3. Tesema was employed as a staff pharmacist by CVS Pharmacy #9967 at the time of the events alleged herein.

4. On or about February 22, 2019, Dr. G.C. submitted an electronic prescription to CVS Pharmacy #9967 for patient D.T. for budesonide 1mg/2ml inhalation suspension for 1 bottle with directions to take 4ml daily with 6 refills: no further directions nor days' supply were specified on the prescription. CVS computer system designated this prescription no. 591151.

5. Pharmaceutical technician Liss Ocampo performed data entry for 60ml (1 box) for a 15-day supply with directions to use 2-unit doses (a total of 4ml) via nebulizer every day. RPh Tesema performed data entry verification, pharmaceutical technician Lizeth Perez-Bailon filled the prescription, Tesema performed final verification and prescription no. 591151 was dispensed to patient D.T. on February 26, 2019.

6. On or about February 27, 2019, the prescriber's office contacted Tesema and clarified that the prescription called for two (2) boxes for a 30-day supply with directions to take orally 4ml per day.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Tesema)

7. Unprofessional conduct includes failing to confer with the person writing or ordering a prescription if there is an error or omission which should be questioned. NAC 639.945(1)(e). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

9. Tesema engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and/or (i) when he failed to contact the prescriber for clarification on prescription no. 591151 and is therefore subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #9967)

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

11. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #9967 is responsible for those violations, including all errors and omissions of Tesema and the pharmaceutical technicians, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 16th day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9967,** **Pharmacy License No. PH01250,** **Respondent.**	**CASE NO. 19-049-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 16th day of NOVEMBER.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9967,** **Pharmacy License No. PH01250,** **Respondent.**	**CASE NO. 19-049-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #9967

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 17th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mihreteab Tesema, RPH
[redacted] Ancala Hollow Ct.
Las Vegas, NV 89148

CVS Pharmacy #9967
950 Village Center Circle
Las Vegas NV 89134

Brian J. Convery, Esq.
200 Campus Drive, Suite 310
Florham Park, NJ 07932

SHIRLEY HUNTING

5B

FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9967,** **Pharmacy License No. PH01250, and** **MIHRETEAB TESEMA, RPH,** **Certificate of Registration No. 18570,** **Respondents.**	**CASE NOS. 19-049-PH-S** **19-049-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Mihreteab Tesema, RPH (Tesema), Certificate of Registration No. 18570, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #9967, Pharmacy License No. PH01250, was a pharmacy licensed by the Board.

2. By Board order entered January 10, 2018, in Case No. 17-032-RPH-S, Tesema stipulated to discipline including a public reprimand and a fine for prescription dispensing errors.

FACTUAL ALLEGATIONS

3. Tesema was employed as a staff pharmacist by CVS Pharmacy #9967 at the time of the events alleged herein.

4. On or about February 22, 2019, Dr. G.C. submitted an electronic prescription to CVS Pharmacy #9967 for patient D.T. for budesonide 1mg/2ml inhalation suspension for 1 bottle with directions to take 4ml daily with 6 refills: no further directions nor days' supply were specified on the prescription. CVS computer system designated this prescription no. 591151.

5. Pharmaceutical technician Liss Ocampo performed data entry for 60ml (1 box) for a 15-day supply with directions to use 2-unit doses (a total of 4ml) via nebulizer every day. RPh Tesema performed data entry verification, pharmaceutical technician Lizeth Perez-Bailon filled the prescription, Tesema performed final verification and prescription no. 591151 was dispensed to patient D.T. on February 26, 2019.

6. On or about February 27, 2019, the prescriber's office contacted Tesema and clarified that the prescription called for two (2) boxes for a 30-day supply with directions to take orally 4ml per day.

COUNT ONE

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Tesema)

7. Unprofessional conduct includes failing to confer with the person writing or ordering a prescription if there is an error or omission which should be questioned. NAC 639.945(1)(e). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

9. Tesema engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and/or (i) when he failed to contact the prescriber for clarification on prescription no. 591151 and is therefore subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #9967)

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

11. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #9967 is responsible for those violations, including all errors and omissions of Tesema and the pharmaceutical technicians, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 16th day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIHRETEAB TESEMA, RPH,** **Certificate of Registration No. 18570,** **Respondent.**	**CASE NO. 19-049-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 16th day of NOVEMBER.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIHRETEAB TESEMA, RPH,** **Certificate of Registration No. 18570,** **Respondent.**	**CASE NO. 19-049-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MIHRETEAB TESEMA, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 17th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mihreteab Tesema, RPH
[redacted]Ancala Hollow Ct.
Las Vegas, NV 89148

CVS Pharmacy #9967
950 Village Center Circle
Las Vegas NV 89134

Brian J. Convery, Esq.
200 Campus Drive, Suite 310
Florham Park, NJ 07932

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9967,** **Pharmacy License No. PH01250, and** **MIHRETEAB TESEMA, RPH,** **Certificate of Registration No. 18570,** **Respondents.**	**CASE NOS. 19-049-PH-S** **19-049-RPH-S** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), Respondent Mihreteab Tesema, RPh (Tesema), Certificate of Registration No. 18570, and Respondent CVS Pharmacy #9967, Pharmacy License No. PH01250, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about November 16, 2023, Respondents were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondents are fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondents do not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Tesema engaged in unprofessional conduct as defined in NAC 639.945(1)(e) and/or (i) when he failed to contact the prescriber for clarification on prescription no. 591151 and is therefore subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12); and

B. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #9967 is responsible for those violations, including all errors and omissions of Tesema and pharmaceutical technicians Liss Ocampo and Lizeth Perez-Bailon, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Mihreteab Tesema, RPh, Certificate of Registration No. 18570, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Tesema shall pay a fine of One Thousand Dollars ($1,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Tesema shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent CVS Pharmacy #9967, Pharmacy License No. PH01250, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent CVS Pharmacy #9967 shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent CVS Pharmacy #9967 shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

9. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

14. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.

15. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of January 2024

CVS PHARMACY #9967
Pharmacy License No. PH01250

Signed this ___ day of January 2024

MIHRETEAB TESEMA, RPH
Certificate of Registration No. 18570

Signed this ___ day of March 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondents Mihreteab Tesema, RPh, Certificate of Registration No. 18570, and CVS Pharmacy #9967, Pharmacy License No. PH01250, in Case Nos. 19-049-PH-S and 19-049-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY,** **Pharmacy License No. PH03347, and** **VENUS VEDADI, RPH,** **Certificate of Registration No. 18969,** **Respondents.**	**CASE NOS. 19-011-PH-S** **19-011-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Venus Vedadi, RPh (Vedadi), Certificate of Registration No. 18969, was a pharmacist registered with the Board, and Respondent ASP Cares Pharmacy, Pharmacy License No. PH03347, was a pharmacy licensed by the Board.

2. By Board order entered October 10, 2018, in Case No. 17-112-RPH-S, Vedadi stipulated to discipline including a fine for unauthorized access of the Prescription Monitoring Program (PMP) database.

FACTUAL ALLEGATIONS

3. Vedadi was employed as managing pharmacist by ASP Cares Pharmacy at the time of the events alleged herein.

4. Vedadi and ASP Cares Pharmacy provided preprinted prescription blanks with ASP Cares Pharmacy information to Kindred Outpatient Wound Care Hospital, located at 5110 W. Sahara Avenue in Las Vegas, directing the prescribing practitioner to fax the prescription to ASP Cares Pharmacy.

5. On or about October 29, 2018, in the course of filling and dispensing prescription no. 170875, and again on December13, 2018, in the course of filling and dispensing prescription no. 174758, both for patient M.K., Vedadi erroneously entered the name of Dr. L.R. on the illegal preprinted prescription blank form as the prescribing practitioner.

6. On or about January 7, 2019, in the course of filling and dispensing prescription no. 176440, submitted on the illegal preprinted prescription blank form, Vedadi erroneously dispensed six (6) 30g tubes of Santyl Ointment to patient L.M. rather than one (1) 30g tube as prescribed by Dr. L.R.

COUNT ONE

Violation of Statutory Prohibition Against Unearned Rebate/Inducement
(Respondents Vedadi and ASP Cares Pharmacy)

7. The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy. NRS 639.264(2).

8. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy. NRS 639.210(12) and (15); NRS 639.220(1).

9. Vedadi and ASP Care Pharmacy violated NRS 639.264(2) by providing preprinted prescription blanks with ASP Cares Pharmacy information to Kindred Wound Care Hospital directing the prescribing practitioner to fax the prescription to ASP Cares Pharmacy, and are subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Vedadi)

10. Unprofessional conduct includes failing to strictly follow the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes failing to confer with the person writing or ordering a prescription if there is an error or omission which should be questioned. NAC 639.945(1)(e). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

11. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

12. Vedadi engaged in unprofessional conduct as defined in NAC 639.945(1)(d), (e) and/or (i) when she and/or pharmaceutical technicians under her supervision committed errors in the course of filling and dispensing prescription nos. 170875, 174758 and 176440, and is subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent ASP Cares Pharmacy)

13. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

14. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent ASP Cares Pharmacy is responsible for those violations, including all

errors and omissions of Vedadi and the pharmaceutical technicians, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 2nd day of January, 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY,** **Pharmacy License No. PH03347,** **Respondent.**	**CASE NO. 19-011-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY,** **Pharmacy License No. PH03347,** **Respondent.**	**CASE NO. 19-011-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR ASP CARES PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Venus Vedadi, RPH
[redacted] Rancho Navarro Street
Henderson, NV 89012

ASP Care Pharmacy
501 S. Rancho Drive Ste. G46
Las Vegas, NV 89106

SHIRLEY HUNTING

5D

FILED
JAN 0 2 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY,** **Pharmacy License No. PH03347, and** **VENUS VEDADI, RPH,** **Certificate of Registration No. 18969,** **Respondents.**	**CASE NOS. 19-011-PH-S** **19-011-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Venus Vedadi, RPh (Vedadi), Certificate of Registration No. 18969, was a pharmacist registered with the Board, and Respondent ASP Cares Pharmacy, Pharmacy License No. PH03347, was a pharmacy licensed by the Board.

2. By Board order entered October 10, 2018, in Case No. 17-112-RPH-S, Vedadi stipulated to discipline including a fine for unauthorized access of the Prescription Monitoring Program (PMP) database.

FACTUAL ALLEGATIONS

3. Vedadi was employed as managing pharmacist by ASP Cares Pharmacy at the time of the events alleged herein.

4. Vedadi and ASP Cares Pharmacy provided preprinted prescription blanks with ASP Cares Pharmacy information to Kindred Outpatient Wound Care Hospital, located at 5110 W. Sahara Avenue in Las Vegas, directing the prescribing practitioner to fax the prescription to ASP Cares Pharmacy.

5. On or about October 29, 2018, in the course of filling and dispensing prescription no. 170875, and again on December13, 2018, in the course of filling and dispensing prescription no. 174758, both for patient M.K., Vedadi erroneously entered the name of Dr. L.R. on the illegal preprinted prescription blank form as the prescribing practitioner.

6. On or about January 7, 2019, in the course of filling and dispensing prescription no. 176440, submitted on the illegal preprinted prescription blank form, Vedadi erroneously dispensed six (6) 30g tubes of Santyl Ointment to patient L.M. rather than one (1) 30g tube as prescribed by Dr. L.R.

COUNT ONE

Violation of Statutory Prohibition Against Unearned Rebate/Inducement
(Respondents Vedadi and ASP Cares Pharmacy)

7. The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy. NRS 639.264(2).

8. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy. NRS 639.210(12) and (15); NRS 639.220(1).

9. Vedadi and ASP Care Pharmacy violated NRS 639.264(2) by providing preprinted prescription blanks with ASP Cares Pharmacy information to Kindred Wound Care Hospital directing the prescribing practitioner to fax the prescription to ASP Cares Pharmacy, and are subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Error in Dispensing Prescription/Unprofessional Conduct

(Respondent Vedadi)

10. Unprofessional conduct includes failing to strictly follow the instructions of a practitioner when filling, labeling, and dispensing a prescription. NAC 639.945(1)(d). Unprofessional conduct also includes failing to confer with the person writing or ordering a prescription if there is an error or omission which should be questioned. NAC 639.945(1)(e). Unprofessional conduct also includes a licensee performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

11. If a pharmaceutical technician performs one or more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription. NAC 639.252 and NAC 639.702

12. Vedadi engaged in unprofessional conduct as defined in NAC 639.945(1)(d), (e) and/or (i) when she and/or pharmaceutical technicians under her supervision committed errors in the course of filling and dispensing prescription nos. 170875, 174758 and 176440, and is subject to discipline pursuant to NAC 639.252, NAC 639.702, NRS 639.210(4) and/or (12).

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

(Respondent ASP Cares Pharmacy)

13. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

14. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent ASP Cares Pharmacy is responsible for those violations, including all

errors and omissions of Vedadi and the pharmaceutical technicians, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 2nd day of January, 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VENUS VEDADI, RPH,** **Certificate of Registration No. 18969,** **Respondent.**	**CASE NO. 19-011-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2ND day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VENUS VEDADI, RPH,** **Certificate of Registration No. 18969,** **Respondent.**	**CASE NO. 19-011-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

VENUS VEDADI, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Venus Vedadi, RPH
[redacted] Rancho Navarro Street
Henderson, NV 89012

ASP Care Pharmacy
501 S. Rancho Drive Ste. G46
Las Vegas, NV 89106

SHIRLEY HUNTING

FILED
JAN 29 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY , License No. PH03347, and** **VENUS VEDADI, RPH, Certificate of Registration No. 151473, and** **Respondents.**	**Case Nos. 19-011-PH-S** **19-011-RPH-S** **ANSWER AND NOTICE OF DEFENSE OF RESPONDENT VENUS VEDADI, RPH**

Respondent Venus Vedadi, RPH., hereby files with the Nevada State Board of Pharmacy ("Board"), her Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on January 2, 2024.

ANSWER TO ACCUSATION

Jurisdiction

Ms. Vedadi agrees that the Board has jurisdiction in this matter as set forth in Paragraphs 1 and 2 of the Accusation. Ms. Vedadi further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 3-6

Paragraph 3: Ms. Vedadi acknowledges being employed by ASP Cares Pharmacy in 2018 and 2019 as the managing pharmacist.

Paragraph 4: Ms. Vedadi denies that she personally provided preprinted prescription blanks with ASP Care Pharmacy information to Kindred Outpatient Wound Care and at no time directed the prescribing practitioner to fax the prescription to ASP Cares Pharmacy.

Paragraph 5: Ms. Vedadi has no independent knowledge as to whether she erroneously entered the name of Dr. L.R. on the prescription provided by Kindred Wound Care Hospital, but does acknowledge that on two prescriptions she entered the practitioner's name as it was on the prescription, however the signature on both prescriptions were sloppy and Ms. Vedadi does not have sufficient personal knowledge to state whether the signature was that of Dr. L.R. or not.

Paragraph 6: Ms. Vedadi is without sufficient personal knowledge to respond to the factual assertions set forth in Paragraph 6 in full, however, to the best of Ms. Vedadi's recollection for any wound treatment, the prescription provided to the pharmacy would typically indicate that the pharmacy was to dispense a sufficient quantity of the prescribed medication for a period of time. The quantity dispensed would be dependent upon the size of the wound, which would have been noted on the prescription. Based on the wound size and the length of time for which the prescription was to be issued, the pharmacist or pharmacy technician would check the website for Santyl which would indicate how much of the drug to dispense for the size. Ms. Vedadi believes that the amount of Santyl Ointment dispensed to the patient at issue would have been based on this type of a calculation.

Counts: Paragraphs 7-14

Count I: Paragraphs 7-9

Paragraph 7: Ms. Vedadi agrees that Paragraph 7 accurately reflects the provisions of NRS 639.264(2).

Paragraph 8: Ms. Vedadi agrees that Paragraph 8 accurately reflects provisions of NRS 639.220(1) but does not reflect the contents of NRS 639.210(12 and (15).

Paragraph 9: Ms. Vedadi denies the allegations contained in Paragraph 9 as they pertain to her personally.

Count II: Paragraphs 10-12

Paragraph 10: Ms. Vedadi asserts that paragraph 10 accurately reflects the contents of NAC 639.945(1)(d),(e), and (i).

Paragraph 11: Ms. Vedadi agrees that Paragraph 11 reflects provisions found in NAC 639.252 and NAC 639.702.

Paragraph 12: Ms. Vedadi denies the allegations set forth in Paragraph 12 and further asserts that the factual allegations contained in the Accusation contain no reference to pharmacy technicians.

Counts III: Paragraphs 13-14

Count lII pertains solely to ASP Cares Pharmacy and requires no response from Ms. Vedadi.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Ms. Vedadi reserves the right to raise any legal defense available to her regarding this matter.

Respectfully submitted this 29th day of January, 2024.

Lyn E. Beggs, Esq.
Attorney for Respondent Venus Vedadi, RPh

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ASP CARES PHARMACY,** **Pharmacy License No. PH03347, and** **VENUS VEDADI, RPH,** **Certificate of Registration No. 18969,** **Respondents.**	**CASE NOS. 19-011-PH-S** **19-011-RPH-S** **STIPULATION AND ORDER** **(RESPONDENT VEDADI ONLY)**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Venus Vedadi, RPh, Certificate of Registration No. 18969, by and through counsel**,** Lyn E. Beggs, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about January 2, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about January 29, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act),

NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Vedadi as managing pharmacist and ASP Care Pharmacy violated NRS 639.264(2) by providing preprinted prescription blanks with ASP Cares Pharmacy information to Kindred Wound Care Hospital directing the prescribing practitioner to fax the prescription to ASP Cares Pharmacy; and

B. Vedadi engaged in unprofessional conduct as defined in NAC 639.945(1)(d), (e) and/or (i) when she and/or pharmaceutical technicians under her supervision committed errors in the course of filling and dispensing prescription nos. 170875, 174758 and 176440.

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 639.210 and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The certificate of registration of Venus Vedadi, RPh, Certificate of Registration No. 18969, is suspended for a period of two (2) years pursuant to NRS 639.255(1)(c). The suspension is

stayed, and Respondent is placed on probation pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding her duties and responsibilities as a registered pharmacist under NRS Chapter 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order; and

D. Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against her while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. 18969 will be fully restored.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately suspend Respondent's Certificate of

Registration No. 18969 and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of March 2024

VENUS VEDADI, RPH,
Certificate of Registration No. 18969

Signed this ___ day of March 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of March 2024

LYN E. BEGGS, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Venus Vedadi, RPh, Certificate of Registration No. 18969, in Case No. 19-011-RPH-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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FILED
JAN 0 2 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAY K. SELZNICK, DMD, MD,** **Certificate of Registration No. CS07913,** **Respondent.**	**CASE NO. 19-043-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Jay K. Selznick, DMD, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS07913, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about December 18, 2015, the Nevada State Board of Dental Examiners (NSBDE) entered an order in Case No. 74127-02801 and imposed discipline on Respondent's License No. S2-22 to practice dentistry for engaging in conduct in violation of standards of practice under NRS 631.3475(1) and NRS 631.230(1)(c) related to prescribing controlled substances to treat pain.

3. Respondent failed to disclose to the Board the disciplinary order in NSBDE Case No. 74127-02801 on his 2016 biennial renewal application for Certificate of Registration No. CS07913.

APPLICABLE LAW

4. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with all applicable standards of care. 21 CFR § 1306.04(a); NRS 453.381(1).

5. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

6. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

8. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

9. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

10. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

11. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has

committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Furnishing False Material Information to Board

12. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 74127-02801 on his 2016 biennial renewal application for Certificate of Registration No. CS07913, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

13. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 74127-02801 on his 2016 biennial renewal application for Certificate of Registration No. CS07913, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT THREE
Violations of Federal and State Law

14. By violating NRS Chapter 631 as detailed in the disciplinary order in NSBDE Case No. 74127-02801, Respondent violated 21 CFR § 1306.04(a) and/or NRS 453.381(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11) and (12).

COUNT FOUR
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By violating NRS Chapter 631 as detailed in the disciplinary order in NSBDE Case No. 74127-02801, and by violating 21 CFR § 1306.04(a) and/or NRS 453.381(1), Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct

contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

16. By failing to disclose to the Board the disciplinary order in NSBDE Case No. 74127-02801 on his 2016 biennial renewal application for Certificate of Registration No. CS07913, by violating NRS Chapter 631 as detailed in the disciplinary order in NSBDE Case No. 74127-02801, and by violating 21 CFR § 1306.04(a) and/or NRS 453.381(1), Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 2nd day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAY K. SELZNICK, DMD, MD,** **Certificate of Registration No. CS07913,** **Respondent.**	**CASE NO. 19-043-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAY K. SELZNICK, DMD, MD,** **Certificate of Registration No. CS07913,** **Respondent.**	**CASE NO. 19-043-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

JAY K. SELZNICK, DMD, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jay K. Selznick, DMD, MD
[redacted]W. Sahara Avenue, Suite 190
Las Vegas, NV 89117

Jay K. Selznick, DMD, MD
[redacted]W. Sahara Ave. #202
Las Vegas, NV 89102

SHIRLEY HUNTING

FILED
JAN 25 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. **JAY K. SELZNICK, DMD, MD,** **Certificate of Registration No. CS07913,** **Respondent.**	**CASE NO. 19-043-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

Jessette Phaynarikone

From: Brett Kandt
Sent: Wednesday, January 24, 2024 8:52 PM
To: Shirley Hunting; Darlene Nases; Jessette Phaynarikone
Subject: Fw: NSBP v. Jay K. Selznick, D.M.D., M.D.

FILED
JAN 25 2024
NEVADA STATE BOARD OF PHARMACY

Please file-stamp, upload and send a copy to me. Thx

From: jay selznick <[redacted]>
Sent: Wednesday, January 24, 2024 7:58 PM
To: Board Coordination <teambc@pharmacy.nv.gov>; Brett Kandt <bkandt@pharmacy.nv.gov>; jay selznick <[redacted]>; Jay Selznick <[redacted]>
Subject: NSBP v. Jay K. Selznick, D.M.D., M.D.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

To: **The Nevada State Board of Pharmacy**
J. David Wuest, Executive Secretary

Re: **Jay K. Selznick CS07913**
Notice of Intended Action and Accusation
Case NO. 10-043-CS-S

I received a Certificate of Service for the above referenced Notice.

I have read it thoroughly and reviewed my records.

In response to the Factual Allegations and COUNTS:

Any failure to disclose to the Board my NSBDE action was **erroneous.**
Any violation of the NRSs and CFRs was **erroneous.**

It has been a lengthy period of time since my NSBDE 2016 disciplinary action. I successfully completed the probationary period.
During the probationary period, my license to practice Oral & Maxillofacial Surgery was NOT restricted. I maintained all of my hospital privileges and appointments. I maintained my provider status with ALL insurance companies.

I would NEVER knowingly withhold any information from a licensing entity - So much so, that when I applied for a New York State DEA number in 2018, they were made aware of my Board action, issued my

DEA number (FS8777382) and had me comply for a 3 year period of prescription monitoring. This was done by way of a letter of Memorandum. It was completed perfectly and monitored by DEA representative - DI Denise Jordan-Group D-62 Program Manager

Since obtaining a NV CS number, this is my first occurrence of this sort. I understand my rights and the Board's claim. I am not retaining counsel and would like to come to a reasonable conclusion to this matter.

Respectfully, I would like to discuss this matter and try to resolve it without the need of a hearing. I would also like to amend and correct my erroneous application from the year in question.

I hereby declare, under the penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts herein stated, are true and correct to the best of my knowledge.

I look forward to hearing from the Board.

Jay K. Selznick, D.M.D., M.D. - January 24th, 2024

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. **KOCHY M.Y. TANG, DO,** **Certificate of Registration No. CS06260,** **Respondent.**	**CASE NO. 19-126-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a first amended notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Kochy M.Y. Tang, DO, held a Nevada controlled substance registration, Certificate of Registration No. CS06260, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent was the medical director of M Family Care, located at 12300 Las Vegas Blvd S in Henderson, Nevada, during the relevant time frames herein.

3. From June 2018 to July 2019, Respondent authorized and directed M Family Care employee Estee Schmidt, RN (RN Schmidt), to independently access, possess, store and administer dangerous drugs to patients, specifically, to provide mobile IV hydration services under the business name of True IVip.

4. With Respondent's knowledge and authorization and at her direction, RN Schmidt provided off-site medical treatment, including the administration of dangerous drugs through

intravenous (IV) therapy and/or injections without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

5. Respondent falsified patient information and issued false prescriptions to Solutions Specialty Pharmacy, located at 8579 S Eastern Avenue in Las Vegas, Nevada, in order to obtain compounded dangerous drugs for office use.

APPLICABLE LAW

6. No person may possess or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

7. A practitioner may give a registered nurse (RN) limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

8. It is a felony offense to falsify a prescription for a dangerous drug or obtain a dangerous drug by a fraudulent prescription. NRS 454.311.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Aiding or abetting a person not licensed to practice in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

12. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

14. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of State Law - Unlawful Possession & Administration of Dangerous Drugs

15. By permitting RN Schmidt to independently access, possess, store and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary,

Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.316, NRS 454.321, NRS 454.356 and NRS 639.100(1), and Respondent is subject to discipline pursuant to NRS 639.210(12).

COUNT TWO

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

16. By permitting RN Schmidt to independently access, possess, store and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary, Respondent performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, aided and abetted RN Schmidt in unlicensed practice, and engaged in, or aided and abetted RN Schmidt to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and Respondent is subject to discipline pursuant to NRS 639.210(4).

COUNT THREE

Violations of State Law — Issuing Fraudulent Prescriptions

17. By falsifying patient information and issuing false prescriptions to Solutions Specialty Pharmacy to obtain compounded dangerous drugs for office use, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.311, and is subject to discipline pursuant to NRS 639.210(12).

COUNT FOUR

Unprofessional Conduct - Issuing Fraudulent Prescriptions

18. By falsifying patient information and issuing false prescriptions to Solutions Specialty Pharmacy to obtain compounded dangerous drugs for office use, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct as defined in NAC 639.945(h), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

19. By permitting RN Schmidt to independently access, possess, store and administer dangerous drugs, without direct practitioner supervision, and without a patient-specific and medication-specific written chart order for the patient and/or medication, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary, and by falsifying patient information and issuing false prescriptions to Solutions Specialty Pharmacy to obtain compounded dangerous drugs for office use, Respondent has committed acts that render her registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 9th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this First Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KOCHY M.Y. TANG, DO,** **Certificate of Registration No. CS06260,** **Respondent.**	**CASE NO. 19-126-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamEC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of FEBRUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KOCHY M.Y. TANG, DO,** **Certificate of Registration No. CS06260,** **Respondent.**	**CASE NO. 19-126-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

KOCHY M.Y. TANG, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of February 2024, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Kochy M.Y. Tang, DO c/o Bridgett Kelly, Esq.
7395 S. Pecos Rd., Suite 103
Las Vegas, NV 89120

SHIRLEY HUNTING
BOARD COORDINATOR

Maria Nutile, Esq.
Nevada Bar No.: 7847
Bridget Kelly, Esq.
Nevada Bar No.: 14388
NUTILE LAW
7395 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89120
Telephone: (702) 307-4880
Facsimile: (702) 307-4881
Email: maria@nutilelaw.com
bridget@nutilelaw.com

Attorneys for Kochy M. Y. Tang, D.O.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. KOCHY M. Y. TANG, D.O. Certificate of Registration No. CS06260, Respondent.	CASE NO.: 19-126-CS-S **ANSWER AND NOTICE OF DEFENSE; REQUEST FOR DISMISSAL PURSUANT TO NRS 622A.360(2)(e) / REQUEST FOR MORE DEFINITE STATEMENT REGARDING THE ALLEGATIONS PURSUANT TO NRS 622A.360(2)(d)**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-titled matter before the Nevada States Board of Pharmacy (the "Board"), declares:

1. That her objections to the Notice of Intended Action and Accusation ("Notice") as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds:

A. Failure to State a Claim. As alleged in the Notice, the allegations in Paragraphs 3 through 5, as reflected in Counts One through Five, violate Dr. Tang's Sixth Amendment rights and are unconstitutionally vague because they fail to apprise the Respondent, with reasonable certainty, of the allegations against her and, thus, deprive her of the ability to prepare a defense. *United States v. Estrada-Iglesias,* 425 F. Supp. 3d 1265, 1269 (D. Nev. 2019). Paragraphs 3 through 5 generally allege that Dr. Tang authorized and directed a non-practitioner employee to

independently access, possess, store and administer dangerous drugs via mobile hydration services, and to administer such services without direct practitioner supervision and without a patient-specific and medication-specific written chart order for the patient and/or medication, and that Dr. Tang failed to establish a bona fide therapeutic relationship with the patients treated by her employee. The Notice fails to specify dates (other than a broad range of thirteen (13) months), times, locations, or patients associated with these alleged events. By failing to identify specific persons and instances on dates certain, the Notice of Intended Action and Accusation deprives Respondent of the ability to defend herself adequately.

B. Lack of Specificity. Paragraph 5 of the Notice, as reflected in Counts Three and Four, allege that Respondent falsified patient information and issued false prescriptions to obtain compounded drugs, thereby participating in fraud or deception. Although Nevada Rules of Civil Procedure do not strictly apply to the adjudication of a contested case (NRS 622A.370), it is well-established that allegations of fraud must be pleaded with specificity as to "the who, what, where, and when of the alleged fraud...to assure that the charge of fraud is responsible and supported, rather than defamatory and extortionate." *Ackerman v. Nw. Mut. Life Ins. Co.,* 172 F.3d 467, 469 (7th Cir. 1999). The Notice fails to provide any specificity as to the alleged falsification(s), and we request that the charges related thereto be dismissed pursuant to NRS 622A.360(2)(e); or, in the alternative, that the Notice be amended to include a more definite statement pursuant to NRS 622A.360(2)(d), with specificity as to the alleged falsification(s) so that Respondent may formulate a defense.

C. Lack of Jurisdiction. Respondent objects to the Board's jurisdiction to prosecute this matter, as (1) all allegations in this case relate to dangerous drugs, and (2) Respondent's authority to prescribe dangerous drugs derives from her licensure under NRS Chapter 633, and not from any authorization issued by the Board. See, NRS 454.00958(1), 454.213(1)(a).

D. The purpose of the foregoing paragraphs was to place the Board on notice of Respondent's legal objections to the Notice. Respondent respectfully reserves the right to brief further and expand upon these objections at the appropriate juncture, if necessary.

2. That, subject to the foregoing objections, in answer to the Notice, she admits, denies, and alleges as follows:

A. With regard to Paragraph 1, Respondent admits that Respondent held and does currently hold Controlled Substance Registration, Certificate No. CS06260, but denies the Board

has jurisdiction in this matter as set forth in Paragraph 1(C) above.

B. With regard to Paragraph 2, Respondent admits the allegations contained therein.

C. With regard to Paragraph 3, Respondent denies the allegations contained therein. Respondent also notes that True IVip was never the business name for M Family Care.

B. With regard to Paragraphs 4 and 5, Respondent denies the allegations therein.

C. Paragraphs 6 through 14 do not contain allegations against the Respondent. To the extent an answer is required, the Respondent denies the allegations in this paragraph.

D. With regard to Paragraphs 15 through 19, Respondent denies the allegations therein.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense; and Request for Dismissal Pursuant to NRS 622A.360(2)(e) / Request for More Definite Statement Regarding the Allegations Pursuant to NRS 622A.360(2)(d), and all facts therein stated, are true and correct to best of my knowledge.

Dated this 24th day of January 2024.

Kochy Tang (Jan 23, 2024 16:10 PST)

KOCHY M. Y. TANG, D.O.

On behalf of Respondent:

NUTILE LAW

/s/ Maria Nutile

Maria Nutile, Esq.
Nevada Bar No.: 7847
Bridget Kelly, Esq.
Nevada Bar No.: 14388
NUTILE LAW
7395 S. Pecos Rd., Suite 103
Las Vegas, Nevada 89120
Telephone: (702) 307-4880
Facsimile: (702) 307-4881
Email: maria@nutilelaw.com
bridget@nutilelaw.com

CERTIFICATE OF SERVICE

I hereby certify that I am an employee of NUTILE LAW, and that on this 24th day of January 2024, I caused to be filed via email an electronic copy of the foregoing Answer and Notice of Defense; and Request for Dismissal Pursuant to NRS 622A.360(2)(e) / Request for More Definite Statement Regarding the Allegations Pursuant to NRS 622A.360(2)(d), to the following at the Nevada State Board of Pharmacy:

Brett Kandt, General Counsel, bkandt@pharmacy.nv.gov

/s/ *Bridget Kelly*
An employee of NUTILE LAW

Answer to Board 01.24.24

Final Audit Report 2024-01-24

Created:	2024-01-23
By:	Bridget Kelly (Bridget@nutilelaw.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAzbBeSdVYsHB6zB3HC7MvVFf1rc-uykB-

"Answer to Board 01.24.24" History

Document created by Bridget Kelly (Bridget@nutilelaw.com)
2024-01-23 - 9:47:14 PM GMT- IP address: 216.17.28.242

Document emailed to [redacted] for signature
2024-01-23 - 9:49:02 PM GMT

Email viewed by [redacted]
2024-01-24 - 0:10:14 AM GMT- IP address: 198.233.183.250

Signer eastmanko@hotmail.com entered name at signing as Kochy Tang
2024-01-24 - 0:10:45 AM GMT- IP address: 198.233.183.250

Document e-signed by Kochy Tang ([redacted])
Signature Date: 2024-01-24 - 0:10:47 AM GMT - Time Source: server- IP address: 198.233.183.250

Agreement completed.
2024-01-24 - 0:10:47 AM GMT

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KOCHY M.Y. TANG, DO,** **Certificate of Registration No. CS06260,** **Respondent.**	**CASE NO. 19-126-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Kochy M.Y. Tang, DO, Certificate of Registration No. CS06260, by and through counsel**,** Bridget Kelly, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about February 9, 2024, Respondent was served with the First Amended Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

4. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to her pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives her rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to her by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent as medical director of M Family Care in Henderson authorized and directed M Family Care employee Estee Schmidt, RN (RN Schmidt) to independently access, possess, store and administer dangerous drugs to patients who have not been examined and diagnosed by a practitioner and without direct practitioner supervision, in violation of NRS 454.213, NRS 454.221, NRS 454.316, NRS 454.316, NRS 454.321, NRS 454.356 and NRS 639.100(1);

B. Respondent performed her duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, aided and abetted RN Schmidt in unlicensed practice, and engaged in, or aided and abetted RN Schmidt to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n);

C. Respondent falsified patient information and issued false prescriptions to Solutions Specialty Pharmacy to obtain compounded dangerous drugs for office use in violation of NRS 454.311 and was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct as defined in NAC 639.945(h); and

D. Respondent has committed acts that render her registration inconsistent with the public interest.

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and/or NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The Respondent Kochy M.Y. Tang, DO, Certificate of Registration No. CS06260, is placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding her duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Two Thousand Five Hundred Dollars ($2,500.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order;

C. Pursuant to NRS 622.400, Respondent shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order;

D. Respondent shall establish and put into practice all necessary policies and procedures to ensure that dangerous drugs are stored, possessed, and administered to patients in compliance with NRS 454.213(1), NRS 454.316, NRS 454.221, NRS 454.321, NRS 454.356 and NRS 639.100(1); and

E. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS06260 will be fully restored.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts

set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of March 2024

KOCHY M.Y. TANG, DO,
Certificate of Registration No. CS06260

Signed this ___ day of March 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of March 2024

BRIDGET KELLY, ESQ.
Counsel for Respondent

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Kochy M.Y. Tang, DO, Certificate of Registration No. CS06260, in Case No. 19-126-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN ROSS, PT,** **Certificate of Registration No. PT20827,** **Respondent.**	**Case No. 20-027-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, was a pharmaceutical technician registered with the Board.

FACTUAL ALLEGATIONS

2. On or about February 4, 2020, Board investigators determined that Respondent was falsely representing himself as a registered pharmacist on social media, specifically Facebook.

COUNT ONE
Violation of State Law

3. Any person who fraudulently represents himself or herself to be a registered pharmacist or practitioner is guilty of a misdemeanor. NRS 639.281(1).

4. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

5. By falsely representing himself to be a registered pharmacist, Respondent violated NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210 (12).

COUNT TWO

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

6. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

7. By falsely representing himself to be a registered pharmacist, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 24th day of June 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN ROSS, PT,** **Certificate Of Registration No. PT20827,** **Respondent.**	**Case No. 20-027-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has scheduled your hearing on this matter for Wednesday, October 11, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 29th day of JUNE, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN ROSS, PT,** **Certificate of Registration No. PT20827,** **Respondent.**	**CASE NO. 20-027-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

RYAN ROSS, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of July, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Ryan Ross, PT
[redacted] Spiracle Ave
Henderson, NV 89002

Jeffrey Setness, Esq.
411 E. Bonneville Ave., Ste. 400
Las Vegas, NV 89101

SHIRLEY HUNTING

FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN ROSS, PT,** **Certificate of Registration No. PT20827,** **Respondent.**	**Case No. 20-027-PT-S** **STIPULATION AND ORDER**

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about June 29, 2023, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that

may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. By falsely representing himself to be a registered pharmacist, Respondent violated NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210(12); and

B. By falsely representing himself to be a registered pharmacist, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).

6. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The registration of Ryan Ross, PT, Certificate of Registration No. PT20827, Ryan Ross, PT, Certificate of Registration No. PT20827, is suspended pursuant to NRS 639.255(1)(c). The suspension is stayed, and Respondent is placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b), subject to the following conditions:

A. Pursuant to NRS 639.255(1)(e), Respondent shall accept this Stipulation and Order as a public reprimand;

B. Pursuant to NRS 639.255(1)(f), Respondent shall pay a fine of Five Hundred Dollars ($500.00) for the violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2023	50.00
11/1/2023	50.00
12/1/2023	50.00
1/1/2024	50.00
2/1/2024	50.00
3/1/2024	50.00
4/1/2024	50.00
5/1/2024	50.00
6/1/2024	50.00
7/1/2024	50.00
TOTAL	**$500.00**

Respondent shall make the monthly payments of the fine by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments;

C. Pursuant to NRS 622.400, Respondent shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, violations, through monthly payments pursuant to the following schedule:

Due Date	Amount
10/1/2023	50.00
11/1/2023	50.00
12/1/2023	50.00
1/1/2024	50.00
2/1/2024	50.00
3/1/2024	50.00
4/1/2024	50.00
5/1/2024	50.00
6/1/2024	50.00
7/1/2024	50.00
TOTAL	**$500.00**

Respondent shall make the monthly payments of the fees and costs by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Respondent has the right to pre-pay any or all of the payments; and

D. Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. PT20827 will be fully restored.

8. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay, immediately suspend Certificate of Registration No. PT20827, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

9. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 6, 2023. Respondent or his counsel may appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

10. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330

and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 2 day of August 2023

RYAN ROSS, PT
Certificate of Registration No. PT20827

Signed this 2 day of August 2023

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, in Case No. 20-027-PT-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this 7th day of September 2023.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 8th day of September 2023, I served a true and correct copy of the foregoing document by Certified Mail to the following:

Ryan Ross
[redacted] Spiracle Ave.
Henderson, NV 89002

9171 9690 0935 0279 1499 40

KRISTOPHER MANGOSING

FILED
JAN 2 5 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RYAN ROSS, PT,** **Certificate of Registration No. PT20827,** **Respondent.**	**Case No. 20-027-PT-N** **ORDER TO SHOW CAUSE**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), makes the following that will serve both a notice of intended action under NRS 233B.127(3) and as an order to show cause under NAC 639.965:

1. Respondent Ryan Ross, PT, Certificate of Registration No. PT20827, is hereby directed to appear before the Board for a hearing to show cause scheduled on March 6, 2024 at the following location:

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

2. On September 6, 2023, the Board and Respondent entered into a Stipulation and Order in Case No. 20-027-PT-N suspending Certificate of Registration No. PT20827 for cause. The suspension was stayed, and Respondent placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b), subject to certain conditions. Pursuant to Paragraphs 7(b) and (c), Respondent agreed to pay pursuant to a payment schedule a fine of Five-Hundred Dollars ($500.00) for the violations, and Five-Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and costs.

3. Respondent has failed to make timely payment of the fine and attorney's fees and costs pursuant to the Stipulation and Order.

4. Respondent is therefore directed to show cause why his Certificate of Registration No. PT20827 should not be subject to further discipline pursuant to NRS Chapter 639.

IT IS SO ORDERED.

Entered this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Ryan Ross, PT
[redacted] Spiracle Ave.
Henderson, NV 89002

SHIRLEY HUNTING

5H

FILED
SEP 18 2023
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AJUMOBI CHARLES AGU, MD,** **Certificate of Registration No. CS21324,** **Respondent.**	**CASE NO. 22-535-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Ajumobi Charles Agu, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS21324, issued by the Board.

FACTUAL ALLEGATIONS

2. On or about June 30, 2023, the Nevada State Board of Medical Examiners (NSBME) entered an order in Case No. 23-12518-1, summarily suspending Respondent's NSBME License No. 8857 to practice medicine for violating prior NSBME disciplinary orders resulting from violations of NRS Chapter 630 related to prescribing controlled substances.

3. On or about July 14, 2023, Board staff served Respondent with notice that the suspension of his NSBME License No. 8857 operated as an immediate suspension of his Certificate of Registration No. CS21324 with the Board pursuant to NRS 639.2107, and that

Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

4. Respondent issued multiple prescriptions for controlled substances after the suspension of his Certificate of Registration No. CS21324.

5. On or about August 10, 2023, the NSBME entered an order in Case No. 23-12518-1, lifting the summary suspension of Respondent's NSBME License No. 8857 to practice medicine; however, Respondent has failed to petition the Board for reinstatement of his Certificate of Registration No. CS21324 pursuant to NRS 639.2565.

APPLICABLE LAW

6. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

7. Falsely representing oneself as a practitioner entitled to write prescriptions in this state is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.321(1)(a); NRS 453.232; NRS 639.2813(1).

8. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

9. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

11. The surrender, revocation or a suspension that has not been stayed of any certificate, license or registration of a practitioner, as defined in NRS 453.126, NRS 454.00958 or NRS 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe or dispense drugs. NRS 639.2107.

12. The pre-hearing suspension of any certificate, license or registration of a practitioner pursuant to NRS 233B.127(3), NRS 453.241(3) and/or NRS 639.2107 is subject to review by the Board. *Barry v. Barchi*, 443 U.S. 55, 99 S. Ct. 2642 (1979); *Spiegel v. Ryan*, 946 F.2d 1435, 1439 (9th Cir. 1991).

COUNT ONE
Violations of Federal Controlled Substances Act

13. By issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS21324, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO
Violations of State Controlled Substances Act

14. By issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS21324, Respondent falsely represented himself as a

practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

15. By violating NRS Chapter 630 as detailed in the NSBME's orders in Case No. 23-12518-1, and by issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS21324, Respondent has performed his duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(4).

COUNT FOUR

Unprofessional Conduct – Prescribing on Suspended Registration

16. By issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS21324, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By violating NRS Chapter 630 as detailed in the NSBME's orders in Case No. 23-12518-1, and by issuing controlled substance prescriptions after the suspension of his Certificate of Registration No. CS21324, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 18th day of SEPTEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AJUMOBI CHARLES AGU, MD,** **Certificate of Registration No. CS21324,** **Respondent.**	**CASE NO. 22-535-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 6, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 1st day of SEPTEMBER, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AJUMOBI CHARLES AGU, MD,** **Certificate of Registration No. CS21324,** **Respondent.**	**CASE NO. 22-535-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

AJUMOBI CHARLES AGU, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 19th day of September 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Ajumobi Charles Agu, MD
[redacted] Faraway St.
Henderson, NV 89074

Ajumobi Charles Agu, MD
[redacted] East Flamingo Suite [redacted]
Las Vegas, NV 89119

SHIRLEY HUNTING

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D., Respondent.**	**Case No.: 23-12518-1**

FILED
JUN 30 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Ajumobi Charles Agu, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated a Board Order when he did not satisfy all of the conditions contained in the Settlement Agreement and Order he entered into with the IC on November 15, 2022, approved by the Board on December 2, 2022.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 8857). The Board issued his license on November 23, 1998.

2. On November 15, 2022, Respondent entered into a Settlement Agreement with the IC and the Board approved the agreement on December 2, 2022. *See* **Exhibit 1** (Settlement Agreement and Order).

///

[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Carl N. Williams, Jr., M.D., FACS, and Col. Eric D. Wade, USAF (Ret.).

3. Per the terms of the Settlement Agreement, Respondent was to submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60) days of the Board's acceptance, adoption, and approval of the Agreement. The Settlement Agreement was approved and adopted on December 2, 2022, requiring completion of the terms on or before January 31, 2023.

4. Additionally, per the Settlement Agreement, Respondent was to perform ten (10) hours of Continuing Medical Education relating to best practices in medical record keeping within six (6) months from the date of the Board's acceptance, adoption, and approval of the Settlement Agreement. The Settlement Agreement was approved and adopted on December 2, 2022, requiring completion of ten (10) hours of Continuing Medical Education to be completed by June 2, 2023.

5. Pursuant to the Settlement Agreement and Order, Respondent agreed that should Respondent fail to comply with any of the terms or conditions of the Agreement, once the Agreement had been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in the State of Nevada pending an Order to Show Cause Hearing, which is hereby duly noticed.

6. Respondent registered for the EBAS examination on March 14, 2023, for an April 25, 2023, exam date.

7. On May 17, 2023, Board staff received notice from Ethics and Boundaries Assessment Services that the Respondent failed all five sections of the EBAS examination which took place on April 25, 2023.

8. On June 28, 2023, Respondent furnished a certificate of completion for the aforementioned hours of Continuing Medical Education with a completion date of June 26, 2023, twenty-four (24) days past the deadline stated in the Settlement Agreement and Order.

9. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with: (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

10. Based on the foregoing, the IC finds that Respondent, Ajumobi Charles Agu, M.D., has willfully and/or knowingly violated his Settlement Agreement and Board Order and is immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1); *see also* BME Case No. 22-12518-1 Settlement Agreement and Order attached hereto as Exhibit 1.

ORDER

IT IS HEREBY ORDERED that the license to practice medicine issued to Ajumobi Charles Agu, M.D. (No. 8857) by the State of Nevada Board of Medical Examiners is immediately **SUSPENDED** until further order of the IC or Board, and Respondent is prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **27th day of July, 2023, at 2:00 p.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time. *See* NRS 630.326(2).

DATED this 30th day of June, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D., Respondent.**	**Case No. 22-12518-1** **FILED** DEC 0 2 2022 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, J.D., Deputy General Counsel for the Board and attorney for the IC, and Ajumobi Charles Agu, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Alia A. Najjar, M.D., Esq., of Ladah Law Firm, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

2. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on November 23, 1998 (License No. 8857).

3. On July 29, 2022, in Case No. 22-12518-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges three (3) violations of NRS 630.301(4) Malpractice (Counts I, IV, VII); three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II, V, VIII); and three (3) violations of NRS 630.306(1)(b)(2) Violation of Standards of Practice by Engaging in

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

the Practice of Writing Prescriptions for Controlled Substances in a Manner that Deviates from the Model Policy (Counts III, VI, IX). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of this Complaint, has reviewed, and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

5. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly, and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Counts I, II, V, VIII: one (1) violation of NRS 630.301(4) Malpractice and three (3) violations of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records.

b. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being four thousand five hundred four dollars and thirty-four cents ($4,504.34).

c. Respondent shall pay a fine of four thousand five hundred dollars and zero cents ($4,500.00) within sixty (60) days of the Board's acceptance, adoption, and approval of this Agreement.

d. Respondent shall perform ten (10) hours of Continuing Medical Education (CME) relating to best practices in medical recordkeeping within six (6) months from the date of the Board's acceptance, adoption, and approval of this agreement. The aforementioned hours of CME shall be in addition to the CME requirements that are regularly imposed for licensure

e. The Respondent shall submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60) days of Board approval of this agreement to be paid for at the expense of the Respondent.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

f. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

g. Respondent shall receive a Public Letter of Reprimand.

h. The remaining counts of the Complaint, and any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this

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Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves, and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed.

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Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 15th day of November, 2022.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS, J.D.
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 14th day of November, 2022.

LADAH LAW FIRM

By: Alia Najjar

ALIA A. NAJJAR, M.D., ESQ.
517 S. Third Street
Las Vegas, NV 89101
Tel: (702) 252-0055
Email: alia@ladahlaw.com
Attorney for Respondent

DATED this 14th day of November, 2021.

By: _____

AJUMOBI CHARLES AGU, M.D.,
Nevada License No. 8857
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

7/7 11-14-2022 14:32:43 17252049077

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 22-12518-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 2nd day of December, 2022.

DATED this 2nd day of December, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 895521
(775) 688-2559

STEVE SISOLAK
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

July 14, 2023

VIA CERTIFIED U.S. MAIL AND ELECTRONIC MAIL TO:
[redacted]

Ajumobi Charges Agu, MD
[redacted] East Flamingo Suite [redacted]
Las Vegas, NV 89119

Re: Suspension of Registration No. CS21324 (Case No. 22-535-CS-S)

Dear Dr. Agu:

The Nevada State Board of Pharmacy (Board) has been notified by the Nevada State Board of Medical Examiners (NSBME) that your NSBME License No. 8857 to practice medicine in Nevada has been suspended in NSBME Case No. 23-12518-1.

Please be advised that pursuant to NRS 639.2107 the suspension of your NSBME License No. 8857 operates as an immediate suspension of your Certificate of Registration No. CS21324 with the Board. You may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until you petition the Board for reinstatement pursuant to NRS 639.2565 and the Board reinstates your certificate of registration. Your PMP account is also suspended pursuant to NAC 453.078.

You may request a hearing before the Board to contest the suspension of your registration by submitting a written request to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

Please be aware that the forgoing does not preclude a formal investigation or filing of an accusation pursuant to NRS 639.241. If you have any questions, please do not hesitate to contact me at 775-850-1440 or bkandt@pharmacy.nv.gov.

Best regards,

Brett Kandt
General Counsel
Nevada State Board of Pharmacy

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D.,** **Respondent.**	**Case No.: 23-12518-1**

FILED

AUG 10 2023

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER LIFTING SUMMARY SUSPENSION

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners having reviewed materials presented at the July 27, 2023 summary suspension hearing of Ajumobi Charles Agu, M.D (Dr. Agu) have concluded that Dr. Agu poses no imminent risk of harm to the health, safety, and welfare of the public or any patient. Accordingly, the IC hereby lifts the summary suspension of Dr. Agu's license to practice medicine in the State of Nevada and the license shall be Active effective the date of this Order.

IT IS SO ORDERED.

DATED this 10th day of August, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D.,** **Respondent.**	**Case No.: 23-12518-1**

FILED

SEP 19 2023

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: [signature]

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Ajumobi Charles Agu, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated the previous Order of Suspension of his license to practice medicine, served on July 6, 2023.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 8857). The Board issued his license on November 23, 1998.

2. On November 15, 2022, Respondent entered into a Settlement Agreement (Agreement) with the IC and the Board approved the Agreement on December 2, 2022. *See* **Exhibit 1** (Settlement Agreement and Order).

3. Per the terms of the Agreement, Respondent was to submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60)

[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Carl N. Williams, Jr., M.D., FACS, and Col. Eric D. Wade, USAF (Ret.).

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Reno, Nevada 89521
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days of the Board's acceptance, adoption, and approval of the Agreement. The Agreement was accepted, adopted, approved, and subsequently filed on December 2, 2022, requiring Respondent to complete the terms of the Agreement on or before January 31, 2023.

4. Additionally, per the Agreement, Respondent was to perform ten (10) hours of Continuing Medical Education (CME) related to the best practices in medical record keeping within six (6) months from the date of the Board's acceptance, adoption, and approval of the Agreement or June 2, 2023.

5. Pursuant to the Agreement and Order, Respondent acceded, that should he fail to comply with any of the terms or conditions of the Agreement, once the Agreement had been accepted, approved, and adopted by the Board, the IC would be authorized to immediately suspend Respondent's license to practice medicine in the State of Nevada pending an Order to Show Cause hearing, which is hereby duly noticed.

6. Respondent registered for the EBAS examination on March 14, 2023, for an April 25, 2023, exam date.

7. On May 17, 2023, Board staff received notice from Ethics and Boundaries Assessment Services that the Respondent failed all five (5) sections of the EBAS examination on April 25, 2023.

8. On June 28, 2023, Respondent furnished a certificate of completion for the aforementioned hours of CME with a completion date of June 26, 2023, twenty-four (24) days past the deadline stated in the Agreement and Order.

9. On June 30, 2023, the IC issued the Respondent an Order of Suspension, which stated unequivocally that the Respondent was prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020. *See* **Exhibit 2** (Order of Suspension and Notice of Hearing, filed June 30, 2023).

10. On July 6, 2023, Respondent was served with aforementioned Order of Suspension.

///

///

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Reno, Nevada 89521
(775) 688-2559

11. An Order to Show Cause Hearing was conducted on July 27, 2023, which was attended by Respondent and Counsel for the IC where it was found that the IC had met its burden of proof to maintain the suspension of Respondent's license to practice medicine.

12. After consideration of the testimony provided at the Order to Show Cause hearing on August 10, 2023, the IC elected to lift the suspension of Respondent's license.

13. On or about August 29, 2023, a prescriber activity report from the Nevada State Board of Pharmacy was retrieved that indicated that Respondent was, in fact, practicing medicine while his license was suspended.

14. Despite Respondent's prohibition from the practice of medicine during the period of his suspension from July 6, 2023, through August 10, 2023, Respondent continued to engage in the practice of medicine without an active Nevada medical license, in violation of the IC's Order of Suspension by writing no less than fifty-eight (58) prescriptions for controlled substances.

15. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with:

> (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

16. Based on the foregoing, the IC finds that Respondent, Ajumobi Charles Agu, M.D., has willfully and/or knowingly violated his Settlement Agreement and Order adopted and issued on December 2, 2022, and then willfully and/or knowingly violated the June 30, 2023, Order of Suspension to which Respondent was immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1); BME Case No. 22-12518-1, Settlement Agreement and Order attached hereto as **Exhibit 1**; Order of Suspension and Notice of Hearing attached hereto as **Exhibit 2**.

ORDER

IT IS HEREBY ORDERED that the license to practice medicine issued to Ajumobi Charles Agu, M.D. (No. 8857) by the State of Nevada Board of Medical Examiners is again immediately **SUSPENDED** until further order of the IC or Board, and **Respondent is**

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prohibited from engaging in *any* acts that constitute the practice of medicine pursuant to NRS 630.020; (emphasis added); and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **19th day of October, 2023, at 2:00 p.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time. *See* NRS 630.326(2).

DATED this 19th day of September, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D.,** **Respondent.**	**Case No. 22-12518-1** **FILED** DEC 0 2 2022 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, J.D., Deputy General Counsel for the Board and attorney for the IC, and Ajumobi Charles Agu, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Alia A. Najjar, M.D., Esq., of Ladah Law Firm, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

2. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on November 23, 1998 (License No. 8857).

3. On July 29, 2022, in Case No. 22-I2518-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges three (3) violations of NRS 630.301(4) Malpractice (Counts I, IV, VII); three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II, V, VIII); and three (3) violations of NRS 630.306(1)(b)(2) Violation of Standards of Practice by Engaging in

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

the Practice of Writing Prescriptions for Controlled Substances in a Manner that Deviates from the Model Policy (Counts III, VI, IX). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of this Complaint, has reviewed, and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

5. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly, and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

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Nevada State Board of Medical Examiners
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Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Counts I, II, V, VIII: one (1) violation of NRS 630.301(4) Malpractice and three (3) violations of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records.

b. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being four thousand five hundred four dollars and thirty-four cents ($4,504.34).

c. Respondent shall pay a fine of four thousand five hundred dollars and zero cents ($4,500.00) within sixty (60) days of the Board's acceptance, adoption, and approval of this Agreement.

d. Respondent shall perform ten (10) hours of Continuing Medical Education (CME) relating to best practices in medical recordkeeping within six (6) months from the date of the Board's acceptance, adoption, and approval of this agreement. The aforementioned hours of CME shall be in addition to the CME requirements that are regularly imposed for licensure

e. The Respondent shall submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60) days of Board approval of this agreement to be paid for at the expense of the Respondent.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

f. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

g. Respondent shall receive a Public Letter of Reprimand.

h. The remaining counts of the Complaint, and any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this

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Nevada State Board of Medical Examiners
9600 Gateway Drive
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(775) 688-2559

Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves, and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed.

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
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Reno, Nevada 89521
(775) 688-2559

Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 15th day of November, 2022.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS, J.D.
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 14th day of November, 2022.

LADAH LAW FIRM

By: Alia Najjar

ALIA A. NAJJAR, M.D., ESQ.
517 S. Third Street
Las Vegas, NV 89101
Tel: (702) 252-0055
Email: alia@ladahlaw.com
Attorney for Respondent

DATED this 14th day of November, 2021.

By: _____

AJUMOBI CHARLES AGU, M.D.,
Nevada License No. 8857
Respondent

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

7/7 11-14-2022 14:32:43 17252049077

ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 22-12518-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 2nd day of December, 2022.

DATED this 2nd day of December, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Board President

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
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EXHIBIT 2

EXHIBIT 2

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of the Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D.,** **Respondent.**	**Case No.: 23-12518-1**

FILED
JUN 30 2023
NEVADA STATE BOARD OF MEDICAL EXAMINERS
By:

OFFICE OF THE GENERAL COUNSEL
Nevada State Board of Medical Examiners
9600 Gateway Drive
Reno, Nevada 89521
(775) 688-2559

ORDER OF SUSPENSION AND NOTICE OF HEARING

The Investigative Committee[1] (IC) of the Nevada State Board of Medical Examiners (Board) hereby **IMMEDIATELY SUSPENDS** the license of Ajumobi Charles Agu, M.D. (Respondent) from the practice of medicine, pursuant to the Board's authority to regulate the practice of medicine in the State of Nevada pursuant to Nevada Revised Statutes (NRS) Chapter 630.

The IC issues this Order of Suspension (Order) based on its determination that Respondent violated a Board Order when he did not satisfy all of the conditions contained in the Settlement Agreement and Order he entered into with the IC on November 15, 2022, approved by the Board on December 2, 2022.

Prior to the preparation of this Order, Board Staff presented to the IC the following:

1. Respondent is a medical doctor licensed to practice medicine in the State of Nevada (License No. 8857). The Board issued his license on November 23, 1998.

2. On November 15, 2022, Respondent entered into a Settlement Agreement with the IC and the Board approved the agreement on December 2, 2022. *See* **Exhibit 1** (Settlement Agreement and Order).

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[1] The Investigative Committee of the Nevada State Board of Medical Examiners is composed of Board members Bret W. Frey, M.D., Carl N. Williams, Jr., M.D., FACS, and Col. Eric D. Wade, USAF (Ret.).

3. Per the terms of the Settlement Agreement, Respondent was to submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60) days of the Board's acceptance, adoption, and approval of the Agreement. The Settlement Agreement was approved and adopted on December 2, 2022, requiring completion of the terms on or before January 31, 2023.

4. Additionally, per the Settlement Agreement, Respondent was to perform ten (10) hours of Continuing Medical Education relating to best practices in medical record keeping within six (6) months from the date of the Board's acceptance, adoption, and approval of the Settlement Agreement. The Settlement Agreement was approved and adopted on December 2, 2022, requiring completion of ten (10) hours of Continuing Medical Education to be completed by June 2, 2023.

5. Pursuant to the Settlement Agreement and Order, Respondent agreed that should Respondent fail to comply with any of the terms or conditions of the Agreement, once the Agreement had been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in the State of Nevada pending an Order to Show Cause Hearing, which is hereby duly noticed.

6. Respondent registered for the EBAS examination on March 14, 2023, for an April 25, 2023, exam date.

7. On May 17, 2023, Board staff received notice from Ethics and Boundaries Assessment Services that the Respondent failed all five sections of the EBAS examination which took place on April 25, 2023.

8. On June 28, 2023, Respondent furnished a certificate of completion for the aforementioned hours of Continuing Medical Education with a completion date of June 26, 2023, twenty-four (24) days past the deadline stated in the Settlement Agreement and Order.

9. NRS 630.3065(2)(a) states in pertinent part that [e]xcept as otherwise provided in NRS 630.2672, knowingly or willfully failing to comply with: (a) [a] regulation, subpoena or order of the Board or a committee designated by the Board to investigate a complaint against a physician, constitutes grounds for initiating disciplinary action.

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10. Based on the foregoing, the IC finds that Respondent, Ajumobi Charles Agu, M.D., has willfully and/or knowingly violated his Settlement Agreement and Board Order and is immediately suspended from the practice of medicine in the State of Nevada. *See* NRS 630.326(1); *see also* BME Case No. 22-12518-1 Settlement Agreement and Order attached hereto as Exhibit 1.

ORDER

IT IS HEREBY ORDERED that the license to practice medicine issued to Ajumobi Charles Agu, M.D. (No. 8857) by the State of Nevada Board of Medical Examiners is immediately **SUSPENDED** until further order of the IC or Board, and Respondent is prohibited from engaging in any acts that constitute the practice of medicine pursuant to NRS 630.020; and

IT IS FURTHER ORDERED that a hearing on this matter is set for the **27th day of July, 2023, at 2:00 p.m.,** at the Board's office located at 9600 Gateway Drive, Reno, Nevada 89521, to determine whether this suspension may continue, unless the parties mutually agree in writing to a different date and/or time. *See* NRS 630.326(2).

DATED this 30th day of June, 2023.

INVESTIGATIVE COMMITTEE OF THE
NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____
BRET W. FREY, M.D.
Chairman of the Investigative Committee

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EXHIBIT 1

EXHIBIT 1

BEFORE THE BOARD OF MEDICAL EXAMINERS OF THE STATE OF NEVADA

* * * * *

In the Matter of Charges and Complaint Against: **AJUMOBI CHARLES AGU, M.D., Respondent.**	**Case No. 22-12518-1** **FILED** DEC 0 2 2022 NEVADA STATE BOARD OF MEDICAL EXAMINERS By:

SETTLEMENT AGREEMENT

The Investigative Committee (IC) of the Nevada State Board of Medical Examiners (Board), by and through Ian J. Cumings, J.D., Deputy General Counsel for the Board and attorney for the IC, and Ajumobi Charles Agu, M.D. (Respondent), a licensed physician in Nevada, assisted by his attorney, Alia A. Najjar, M.D., Esq., of Ladah Law Firm, hereby enter into this Settlement Agreement (Agreement) based on the following:[1]

A. BACKGROUND

2. Respondent is a medical doctor currently licensed in active status by the Board pursuant to Chapter 630 of the Nevada Revised Statutes (NRS) and Chapter 630 of the Nevada Administrative Code (NAC) (collectively, the Medical Practice Act) to practice medicine in Nevada. His license was originally issued on November 23, 1998 (License No. 8857).

3. On July 29, 2022, in Case No. 22-12518-1, the IC filed a formal Complaint (Complaint) charging Respondent with violating the Medical Practice Act. Specifically, the Complaint alleges three (3) violations of NRS 630.301(4) Malpractice (Counts I, IV, VII); three (3) violations of NRS 630.3062(1)(a), Failure to Maintain Proper Medical Records (Counts II, V, VIII); and three (3) violations of NRS 630.306(1)(b)(2) Violation of Standards of Practice by Engaging in

[1] All agreements and admissions made by Respondent are solely for final disposition of this matter and any subsequent related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another state or federal government regulatory agency proceeding, state or federal civil or criminal proceeding, any state or federal court proceeding, or any credentialing or privileges matter.

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the Practice of Writing Prescriptions for Controlled Substances in a Manner that Deviates from the Model Policy (Counts III, VI, IX). By reason of the foregoing, Respondent is subject to discipline by the Board as provided in NRS 630.352.

4. Respondent was properly served with a copy of this Complaint, has reviewed, and understands this Complaint, and has had the opportunity to consult with competent counsel concerning the nature and significance of this Complaint.

5. Respondent is hereby advised of his rights regarding this administrative matter, and of his opportunity to defend against the allegations in the Complaint. Specifically, Respondent has certain rights in this administrative matter as set out by the United States Constitution, the Nevada Constitution, the Medical Practice Act, the Nevada Open Meeting Law (OML), which is contained in NRS Chapter 241, and the Nevada Administrative Procedure Act (APA), which is contained in NRS Chapter 233B. These rights include the right to a formal hearing on the allegations in the Complaint, the right to representation by counsel, at his own expense, in the preparation and presentation of his defense, the right to confront and cross-examine the witnesses and evidence against him, the right to written findings of fact, conclusions of law and order reflecting the final decision of the Board, and the right to judicial review of the Board's order, if the decision is adverse to him.

6. Respondent understands that, under the Board's charge to protect the public by regulating the practice of medicine, the Board may take disciplinary action against Respondent's license, including license probation, license suspension, license revocation and imposition of administrative fines, as well as any other reasonable requirement or limitation, if the Board concludes that Respondent violated one or more provisions of the Medical Practice Act.

7. Respondent understands and agrees that this Agreement, by and between Respondent and the IC, is not with the Board, and that the IC will present this Agreement to the Board for consideration in open session at a duly noticed and scheduled meeting. Respondent understands that the IC shall advocate for the Board's approval of this Agreement, but that the Board has the right to decide in its own discretion whether or not to approve this Agreement. Respondent further understands and agrees that if the Board approves this Agreement, then the terms and conditions enumerated below shall be binding and enforceable upon him and the Board.

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B. TERMS & CONDITIONS

NOW, THEREFORE, in order to resolve the matters addressed herein, i.e., the matters with regard to the Complaint, Respondent and the IC hereby agree to the following terms and conditions:

1. **Jurisdiction**. Respondent is, and at all times relevant to the Complaint has been, a physician licensed to practice medicine in Nevada subject to the jurisdiction of the Board as set forth in the Medical Practice Act.

2. **Representation by Counsel/Knowing, Willing and Intelligent Agreement**. Respondent acknowledges he is represented by counsel and wishes to resolve the matters addressed herein with said counsel. Respondent agrees that if representation by counsel in this matter materially changes prior to entering into this Agreement and for the duration of this Agreement, that counsel for the IC will be timely notified of the material change. Respondent agrees that he knowingly, willingly, and intelligently enters into this Agreement after deciding to have a full consultation with and upon the advice of legal counsel.

3. **Waiver of Rights**. In connection with this Agreement, and the associated terms and conditions, Respondent knowingly, willingly and intelligently waives all rights in connection with this administrative matter. Respondent hereby knowingly, willingly and intelligently waives all rights arising under the United States Constitution, the Nevada Constitution, the Medical Practice Act, the OML, the APA, and any other legal rights that may be available to him or that may apply to him in connection with the administrative proceedings resulting from the Complaint filed in this matter, including defense of the Complaint, adjudication of the allegations set forth in the Complaint, and imposition of any disciplinary actions or sanctions ordered by the Board. Respondent agrees to settle and resolve the allegations of the Complaint as set out by this Agreement, without a hearing or any further proceedings and without the right to judicial review.

4. **Acknowledgement of Reasonable Basis to Proceed**. As of the time of entering into this Settlement Agreement, the allegations of the Complaint remain unproven. Respondent acknowledges that the IC believes it has a reasonable basis to allege that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. The IC acknowledges

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Respondent is not admitting that the IC's claims/counts as alleged in the Complaint have merit and Respondent is agreeing to resolve this matter to avoid the costs of hearing and potential subsequent litigation. Respondent asserts if this matter were to proceed to hearing, he has evidence, witnesses, expert witness(es) and defenses to the counts/claims alleged in the Complaint, but for the purposes of resolving the matter and for no other purpose, Respondent waives the presentation of evidence, witnesses, expert witnesses, and defenses in order to effectuate this Agreement.

5. **Consent to Entry of Order**. In order to resolve this Complaint pending against Respondent, Respondent hereby agrees that the Board may issue an order finding that Respondent engaged in conduct that is grounds for discipline pursuant to the Medical Practice Act. Accordingly, the following terms and conditions are hereby agreed upon:

a. Respondent admits to Counts I, II, V, VIII: one (1) violation of NRS 630.301(4) Malpractice and three (3) violations of NRS 630.3062(1)(a) Failure to Maintain Proper Medical Records.

b. Respondent will pay the costs and expenses incurred in the investigation and prosecution of the above-referenced matter within sixty (60) days of the Board's acceptance, adoption and approval of this Agreement, the current amount being four thousand five hundred four dollars and thirty-four cents ($4,504.34).

c. Respondent shall pay a fine of four thousand five hundred dollars and zero cents ($4,500.00) within sixty (60) days of the Board's acceptance, adoption, and approval of this Agreement.

d. Respondent shall perform ten (10) hours of Continuing Medical Education (CME) relating to best practices in medical recordkeeping within six (6) months from the date of the Board's acceptance, adoption, and approval of this agreement. The aforementioned hours of CME shall be in addition to the CME requirements that are regularly imposed for licensure

e. The Respondent shall submit to and pass all five (5) sections of the Ethics and Boundaries Assessment Services (EBAS) examination within sixty (60) days of Board approval of this agreement to be paid for at the expense of the Respondent.

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f. This Agreement shall be reported to the appropriate entities and parties as required by law, including, but not limited to, the National Practitioner Data Bank.

g. Respondent shall receive a Public Letter of Reprimand.

h. The remaining counts of the Complaint, and any other claims arising from the Board's corresponding investigative case file(s), shall be dismissed with prejudice.

6. **Release from Liability**. In execution of this Agreement, Respondent understands and agrees that the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents are immune from civil liability for any decision or action taken in good faith in response to information acquired by the Board. NRS 630.364(2)(a). Respondent agrees to release the State of Nevada, the Board, and each of its members, staff, counsel, investigators, experts, peer reviewers, committees, panels, hearing officers, consultants and agents from any and all manner of actions, causes of action, suits, debts, judgments, executions, claims and demands whatsoever, known and unknown, in law or equity, that Respondent ever had, now has, may have or claim to have, against any or all of the persons, government agencies or entities named in this paragraph arising out of, or by reason of, this investigation, this Agreement or the administration of the case referenced herein.

7. **Procedure for Adoption of Agreement**. The IC and counsel for the IC shall recommend approval and adoption of the terms and conditions of this Agreement by the Board in resolution of this Complaint. In the course of seeking Board acceptance, approval and adoption of this Agreement, counsel for the IC may communicate directly with the Board staff and the adjudicating members of the Board.

Respondent acknowledges that such contacts and communications may be made or conducted ex-parté, without notice or opportunity to be heard on his part until the public Board meeting where this Agreement is discussed, and that such contacts and communications may include, but may not be limited to, matters concerning this Agreement, the Complaint and any and all information of every nature whatsoever related to this matter. The IC and its counsel agree that Respondent and/or Counsel for the Respondent may appear at the Board meeting where this

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Agreement is discussed and, if requested, respond to any questions that may be addressed to the IC or the IC's counsel.

8. **Effect of Acceptance of Agreement by Board**. In the event the Board accepts, approves, and adopts this Agreement, the Board shall issue a final order, making this Agreement an order of the Board, and, pending full compliance with the terms herein, the case shall be closed and all remaining claims arising out of the Complaint shall be dismissed with prejudice.

9. **Effect of Rejection of Agreement by Board**. In the event the Board does not accept, approve and adopt this Agreement, this Agreement shall be null, void and of no force and effect except as to the following agreement regarding adjudications: (1) Respondent agrees that, notwithstanding rejection of this Agreement by the Board, nothing contained in this Agreement and nothing that occurs pursuant to efforts of the IC to seek the Board's acceptance of this Agreement shall disqualify any member of the adjudicating panel of the Board from considering this Complaint and from participating in disciplinary proceedings against Respondent, including adjudication of this case; and (2) Respondent further agrees that he shall not seek to disqualify any such member absent evidence of bad faith.

10. **Binding Effect**. If approved by the Board, Respondent understands that this Agreement is a binding and enforceable contract upon Respondent and the Board.

11. **Forum Selection Clause**. The parties agree that in the event either party is required to seek enforcement of this Agreement in district court, the party's consent to such jurisdiction and agree that exclusive jurisdiction shall be in the Second Judicial District Court, State of Nevada, Washoe County.

12. **Attorneys' Fees and Costs**. The parties agree that in the event an action is commenced in district court to enforce any provision of this Agreement, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs.

13. **Failure to Comply with Terms**. Should Respondent fail to comply with any term or condition of this Agreement once the Agreement has been accepted, approved, and adopted by the Board, the IC shall be authorized to immediately suspend Respondent's license to practice medicine in Nevada pending an Order to Show Cause Hearing, which will be duly noticed.

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Failure to comply with the terms of this Agreement, including failure to pay any fines, costs, expenses or fees owed to the Board, is a failure to comply with an order of the Board, which may result in additional disciplinary action being taken against Respondent. NRS 630.3065(2)(a).

Further, Respondent's failure to remit payment to the Board for monies agreed to be paid as a condition of this Agreement may subject Respondent to civil collection efforts.

DATED this 15th day of November, 2022.

INVESTIGATIVE COMMITTEE OF THE NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

IAN J. CUMINGS, J.D.
Deputy General Counsel
9600 Gateway Drive
Reno, NV 89521
Tel: (775) 688-2559
Email: icumings@medboard.nv.gov
Attorney for the Investigative Committee

DATED this 14th day of November, 2022.

LADAH LAW FIRM

By: Alia Najjar

ALIA A. NAJJAR, M.D., ESQ.
517 S. Third Street
Las Vegas, NV 89101
Tel: (702) 252-0055
Email: alia@ladahlaw.com
Attorney for Respondent

DATED this 14th day of November, 2021.

By: _____

AJUMOBI CHARLES AGU, M.D.,
Nevada License No. 8857
Respondent

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ORDER

IT IS HEREBY ORDERED that, the foregoing Settlement Agreement (Case No. 22-12518-1) was approved and accepted by the Nevada State Board of Medical Examiners on the 2nd day of December, 2022.

DATED this 2nd day of December, 2022.

NEVADA STATE BOARD OF MEDICAL EXAMINERS

By: _____

AURY NAGY, M.D.
Board President

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONIVIRIN SON, MD,** **Certificate of Registration No. CS35699,** **Respondent.**	**CASE NO. 23-046-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the alleged events, Respondent Monivirin Son, MD, held expired Nevada controlled substance registrations, Certificate of Registration Nos. CS25265, CS12420, and CS15562, and/or a provisional Nevada controlled substance registration, CS35699, all issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562, all of which expired on October 31, 2018.

3. Respondent issued two thousand six hundred and eighty-four (2,684) prescriptions for controlled substances via telehealth to four hundred and eighty-four (484) patients in Nevada between November 1, 2018, and June 21, 2023, without a valid Nevada controlled substance registration and without accessing the Prescription Monitoring Program (PMP) database to review a patient utilization report.

4. On or about June 14, 2023, Respondent submitted an application to the Board for a new Nevada controlled substance registration, representing that his practice was located at 504 San Pablo Drive – APT 202, Las Vegas, NV 89104.

5. On or about June 22, 2023, Respondent was issued a new controlled substance registration, Certificate of Registration No. CS35699. However, Respondent failed to submit proof of his registration with the U.S. Drug Enforcement Administration pursuant to 21 U.S.C. § 822(a)(2) to the Board, and failed to enroll with the Board for Internet access to the PMP database.

6. Since June 22, 2023, Respondent has issued no fewer than eight hundred and six (806) prescriptions for controlled substances to patients in Nevada without complying with all requirements for prescribing under a Nevada controlled substance registration and without accessing the PMP database to review a patient utilization report.

7. On or about December 6, 2023, Respondent was served with an order pursuant to NRS 639.2895(1) to cease and desist possessing (except pursuant to the lawful order of a practitioner), administering, prescribing or dispensing any controlled substance under Certification of Registration No. CS35699 until he submits proof of registration with the U.S. Drug Enforcement Administration to the Board and enrolls with the Board for Internet access to the PMP database.

8. On or about December 12, 2023, Respondent admitted to the Executive Secretary that he does not practice at 504 San Pablo Drive – APT 202 in Las Vegas.

APPLICABLE LAW

9. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.232; NRS 453.321(1)(a); NRS 629.515(1); NRS 639.100(1); NRS 639.235(1).

10. A practitioner must present proof that he or she is authorized to access the PMP database to hold a valid Nevada controlled substance registration. NRS 453.226(1); NAC 453.065.

11. Falsely representing oneself as a practitioner entitled to issue prescriptions in this state, and unlawfully issuing a prescription for a controlled substance in this state, are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.232; NRS 453.321(1)(a); NRS 639.2813(1).

12. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 453. NRS 453.331(1)(e); NRS 639.281(1).

13. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct and conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

16. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

17. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

18. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. The Board may suspend or revoke a registration if the holder has failed to timely renew a certificate of registration by failing to submit the application for renewal. NRS 639.210(13).

21. The Board may suspend or revoke a registration to prescribe a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest as determined pursuant to NRS 453.231. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of Federal Controlled Substances Act

22. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO
Violations of State Controlled Substances Act

23. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration as alleged herein, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 629.515(1), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE
Failure to Time Renew Controlled Substance Registration

24. By failing to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562, and subsequently issuing prescriptions for controlled substances, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(13).

COUNT FOUR
Furnishing False Material Information to Board

25. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

COUNT FIVE
Obtaining Registration by False or Fraudulent Application

26. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

COUNT SIX

Unprofessional Conduct – Fraudulent or Deceitful Practice or Transaction

27. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1(h) and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT SEVEN

Unprofessional Conduct – Prescribing without a Valid Registration

28. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration as alleged herein, Respondent performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i) and (k), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT

Commission of Acts that Render Registration Inconsistent with the Public Interest

29. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration as alleged herein, by falsely representing himself as a practitioner entitled to issue prescriptions in this state, and by falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(a) and (e) and/or NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 14th day of December, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONIVIRIN SON, MD,** **Certificate of Registration No. CS35699,** **Respondent.**	**CASE NO. 23-046-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and bkandt@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 14th day of DECEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONIVIRIN SON, MD,** **Certificate of Registration No. CS35699,** **Respondent.**	**CASE NO. 23-046-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MONIVIRIN SON, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 14th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Monivirin Son
[redacted]San Pablo Drive Ste 202
Las Vegas, NV 89104

Monivirin Son
[redacted] W Sahara Ave
Las Vegas, NV 89117

Monivirin Son
[redacted] Bosque
Irvine, CA 92628

Darlene Nases
DARLENE NASES

FILED
JAN 25 2024
NEVADA STATE BOARD
OF PHARMACY

Before the Nevada State Board of Pharmacy

Nevada State Board of Pharmacy, Petitioner.
v.
Monivirin Son, MD,
Certificate of Registration No. CS35699, Respondent.

Case No. 23-046 – CS – S
Answer And Notice Of Defense.

Responded above name, in answer to the notice of
Intended Action and Accusation, filed in the above– entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and accusation, as being incomplete, or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: None

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies, and all ledges, as follows:

In 2018, I had 3 Nevada Controlled Substance Registrations when I worked for University Medical Center of Southern Nevada Quick-cares, Laborers/Pipe-Fitters Union clinic and Southwest Medical Urgent Cares. In the latter parts of 2018, after 10+ years in Las Vegas, Nevada, I transitioned to California and the 3 CSL - Control Substance Registrations expired in Aug 2018.

Towards the end of 2018, I initially worked in California prisons - CDCR and California jail system. This included several CDCR - California prisons: CHCF - California Health Care Facility, San Joaquin county, California State Prison in Sacramento, Mule Creek State Prison in Amador county, Salinas Valley State Prison in Monterey county, and Valley State Prison in Madera county. In 2018, I also began work in California state jail system in Amador, Calaveras and Tuolumne counties - both adult/juvenile facilities.

When COVID outbreak started, I continued to work in the prison and jail systems doing both Primary Care and ISUDT - Integrated Substance Use Disorder Treatment program - both in-person and telemedicine capacities. The ISUDT

program uses the American Society of Addiction Medicine - ASAM criteria - the treatment criteria for addictive substance related and co-occurring conditions. The ASAM criteria was created to improve the quality of and access to addiction care. The principles concepts and criteria of ASAM is to promote good stewardship of resources in addiction, mental health and general healthcare systems. The criteria provide a way to match individual suffering from addiction with the services and tools they need for successful and long-term recovery.

California prisons used Buprenorphine-Naloxone vs the California jails used Buprenorphine as the Medication in their respective program. As COVID progressed, I also started working for QuickMD as a telemedicine only addiction medicine specialist based in California. For QuickMD, I prescribe both Buprenorphine and Buprenorphine-Naloxone - for the following states - California, Florida, Texas, Colorado, Ohio, Nevada, Michigan, Mississippi, Hawaii, and Wisconsin.

Working initially only in California, I used the State of California's Prescription Drug Monitoring Program (CURES) - which on the website has not only California, but can add interstate search for other states - including pending for Nevada. Therefore, I did not do the individual PDMP for other states at that time.

Recently, between May 2023 through September 2023, I transitioned from California Prison Primary care physician/ISUDT treatment physician to an ISUDT physician for American Health Services/El Dorado Community Service Centers in Southern California serving several cities including Pico Rivera, Hawaiian Gardens, Lawndale, Long Beach, and Azusa. The Southern California ISUDT program uses Methadone, Buprenorphine and Buprenorphine-Naloxone as medication choices. I can travel from my home in Southern California, rather than rent an apartment and move every 3 to 6 months if I continued to work in the California prisons. In summary, I continue employment at three places: California state jail system in Amador, Calaveras, and Tuolumne counties (both in person and telemedicine), American Health Services/El Dorado Community Service Centers in Southern California (in person only) and QuickMD (telemedicine only). In all three places of employment, I work as an ISUDT, Integrated Substance Use Disorder Treatment physician using ASAM - American Society of Addiction Medicine criteria to improve quality of and access to addiction care.

The notice from the State Board of Pharmacy - filed 12-14-23 states the following with my answers:

1) The notice states that I failed to renew your Certificate of Registration, which expired on October 31, 2018. Yes, this accurate.

2) The notice states that I issued 2,684 prescriptions for controlled substances via tele-health to 484 patients in Nevada between November 1, 2018, and June 21, 2023 without a valid Nevada controlled substance registration and without accessing the PMP database. Yes, this accurate.

3) The notice states when I was issued a new controlled substance registration on June 22, 2023, I failed to submit proof of your registration to the U.S. Drug Enforcement Administration and that I failed to enroll with the Board for Internet access to the PMP database. Yes, this accurate.

4) Since June 22, 2023, I have issued no fewer than 806 prescriptions for controlled substances to patients in Nevada without complying with all requirements for prescribing under a Nevada controlled substance registration and without accessing the PMP database to review a patient utilization report. Yes, this is accurate.

After notification from the Nevada State Board of Pharmacy, I had the opportunity to and did make the following corrections:

1] Update CSL applications - Control Substance Registration to those states that require State Board of Pharmacy documentation - Hawaii, Michigan and Nevada.

2] Register and use the PDMP - Prescription Drug Monitoring Program for all individual states I am licensed in: California, Florida, Texas, Colorado, Ohio, Nevada, Michigan, Mississippi, Hawaii, and Wisconsin.

3] Respond to the State of Nevada Board of Pharmacy December 6, 2023 Cease and Desist/Citation – I submitted proof of my registration with the US drug enforcement administration to the Board and enrolled with the Board for Internet access to the prescription monitoring program database. On December 19, 2023 the State of Nevada Board Pharmacy lifted the order to cease and desist.

What I realized during this process is that I should found it meaningful to take the extra step and do individual state PDMP rather than wait for the State of California Prescription Drug Monitoring Program (CURES) to activate pending interstate search modules. I should have monitored which states require Controlled Substance Registrations - State Board of Pharmacy applications. I should have called the Nevada State Board of Pharmacy regarding my options for the Nevada address for QuickMD telemedicine services rather than Google the address. I do want to express my apologies and look forward to work with the Nevada State Board of Pharmacy to make current and future corrections as needed.

I hereby declare, under penalty of perjury, that the foregoing Answer, and Notice

of Defense, and all facts therein stated, are true, and correct to the best of my knowledge.

Dated this 24th day of January, 2024.

Monivirin Son, MD

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MONIVIRIN SON, MD,** **Certificate of Registration No. CS35699,** **Respondent.**	**Case No. 23-046-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through General Counsel Brett Kandt, and Respondent Monivirin Son, MD, Certificate of Registration No. CS35699, **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about December 14, 2023, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing, and Respondent filed an Answer and Notice of Defense to the Accusation on or about January 25, 2024.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions

of this Stipulation, Respondent hereby freely and voluntarily waives his rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. Respondent failed to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562, all of which expired on October 31, 2018.

B. Respondent issued two thousand six hundred and eighty-four (2,684) prescriptions for controlled substances via telehealth to four hundred and eighty-four (484) patients in Nevada between November 1, 2018, and June 21, 2023, without a valid Nevada controlled substance registration and without accessing the Prescription Monitoring Program (PMP) database to review a patient utilization report.

C. On or about June 14, 2023, Respondent submitted an application to the Board for a new Nevada controlled substance registration, representing that his practice was located at 504 San Pablo Drive – APT 202, Las Vegas, NV 89104.

D. On or about June 22, 2023, Respondent was issued a new controlled substance registration, Certificate of Registration No. CS35699. However, Respondent failed to submit proof of his registration with the U.S. Drug Enforcement Administration pursuant to 21 U.S.C. § 822(a)(2) to the Board, and failed to enroll with the Board for Internet access to the PMP database.

E. Since June 22, 2023, Respondent has issued no fewer than eight hundred and six (806) prescriptions for controlled substances to patients in Nevada without complying with all requirements for prescribing under a Nevada controlled substance registration and without accessing the PMP database to review a patient utilization report.

F. On or about December 6, 2023, Respondent was served with an order pursuant to NRS 639.2895(1) to cease and desist possessing (except pursuant to the lawful order of a practitioner), administering, prescribing or dispensing any controlled substance under Certification of Registration No. CS35699 until he submits proof of registration with the U.S. Drug Enforcement Administration to the Board and enrolls with the Board for Internet access to the PMP database.

G. On or about December 12, 2023, Respondent admitted to the Executive Secretary that he does not practice at 504 San Pablo Drive – APT 202 in Las Vegas.

H. On or about December 19, 2023, the cease-and-desist order was lifted after Respondent submitted proof of registration with the U.S. Drug Enforcement Administration to the Board and enrolled with the Board for Internet access to the PMP database.

I. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. **§** 822(a)(2), 21 U.S.C. **§** 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a) and/or 21 CFR § 1306.03(a)(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

J. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration, Respondent falsely represented himself as a practitioner entitled to write prescriptions in this state and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.232, NRS 453.321(1)(a), NRS 629.515(1), NRS 639.100(1), NRS 639.235(1)and/or NRS 639.2813(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(12).

K. By failing to timely renew his Certificate of Registration Nos. CS25265, CS12420, and CS15562, and subsequently issuing prescriptions for controlled substances, Respondent is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(13).

L. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent violated NRS 453.331(l)(e) and NRS 639.281(1), and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1), NRS 639.210(9) and/or NRS 639.210(12).

M. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(10).

N. By falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1(h) and is subject to discipline pursuant to NRS 453.236(1)(a) and (e), NRS 453.241(1) and/or NRS 639.210(4).

O. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration, Respondent performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i) and (k), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

P. By issuing prescriptions for controlled substances to patients in Nevada without a valid registration, by falsely representing himself as a practitioner entitled to issue prescriptions in this state, and by falsely representing on his application for a new Nevada controlled substance registration that his practice was located at 504 San Pablo Drive – APT 202 in Las Vegas, Respondent committed acts that render his registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1)(a) and (e) and/or NRS 453.241(1).

8. Those violations are plead with particularity in the Accusation, and are grounds for action pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210 and NRS 639.255.

9. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. The certificate of registration of Respondent Monivirin Son, MD, Certificate of Registration No. CS35699, is suspended for a period of two (2) years pursuant to NRS 453.241(1)(a). The suspension is stayed, and Respondent is placed on probation pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Respondent shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a practitioner under NRS Chapters 453, 454 and 639;

B. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Two Thousand Dollars ($2,000.00) for each of the eight (8) causes of action in the Accusation, for a total of Sixteen Thousand Dollars ($16,000.00), by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order;

C. Pursuant to NRS 622.400, Respondent shall pay Two Thousand Five Hundred Dollars ($2,500.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order;

D. Respondent shall establish and put into practice all necessary policies and procedures to ensure that any prescription complies with the provisions of federal and state law and shall be subject to quarterly PMP compliance checks; and

E. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS35699 will be fully restored.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately suspend Respondent's Certificate of Registration No. CS35699 and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Respondent shall appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of March 2024

MONIVIRIN SON, MD,
Certificate of Registration No. CS35699

Signed this ___ day of March 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent Monivirin Son, MD, Certificate of Registration No. CS35699, in Case No. 23-046-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5J

FILED
SEP 28 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a first amended notice of intended action under NRS 233B.127(3) and a first amended accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

FACTUAL ALLEGATIONS

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120) prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as alleged above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied then to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) were not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay $330,000 in restitution, and Respondent was sentenced to probation and ordered to pay $300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of $100,000, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. However, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the

conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he did not disclose the individual charges and/or arrests related to the felony fraud charges mentioned in paragraphs 10 and 14 above.

APPLICABLE LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE
Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribed controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO
Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE
Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR
Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct, Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE
Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN

Failure to Establish Bona Fide Patient Relationships

39. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

40. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

COUNT EIGHT
Conviction of Crime Involving Dishonesty

41. As described above, Respondent was convicted of intentional failure to maintain adequate records, a gross misdemeanor.

42. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent.

43. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, amounted to a conviction for a crime involving dishonesty. The Board may impose administrative discipline based upon that conviction. *See* NRS 639.210(7)(c).

COUNT NINE
Willfully Making False Statements in Connection with Renewal Application

44. As alleged above, on or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. On the application, Respondent falsely represented that he had never been charged with or arrested for a criminal offense other than a misdemeanor offense related to record keeping. When he made this representation, Respondent had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

45. When he made the above false representation, Respondent knew that he had recently been charged with and/or arrested for multiple felony offenses related to a scheme to defraud Medicaid.

46. Respondent's false statement was material to the Board's determination whether to renew Respondent's certificate of registration to prescribe controlled substances.

47. Having willfully made a false representation as alleged above, Respondent is subject to discipline pursuant to NRS 639.210(9).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 26th day of September 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this First Amended Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you, as is more fully explained and set forth in the First Amended Notice of Intended Action and Accusation served herewith and hereby incorporated reference herein.

2. You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the First Amended Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Statement and Notice, and of the First Amended Notice of Intended Action and Accusation served within. NRS 622A.320; NRS 639.243.

3. **The Board has rescheduled your hearing on this matter for Wednesday, December 6, 2023, at 9:00 AM PST or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of September, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, MD,** **Certificate of Registration No. CS10935,** **Respondent.**	**CASE NO. 19-013-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

MATTHEW OKEKE, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of September 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
[redacted] S. Las Vegas Blvd., [redacted]
Las Vegas, NV 89101

SHIRLEY HUNTING

FILED
JAN 17 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. MATTHEW OKEKE, M.D., Certificate of Registration No. CS10935, Respondent.	Case No. 19-013-CS-S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

This matter came before the Nevada State Board of Pharmacy at its regularly scheduled meeting on Wednesday, January 17, 2024. Gregory L. Zunino, Senior General Counsel, prosecuted the case before the Board. Respondent Matthew Okeke, M.D., Certificate of Registration No. CS10935, failed to appear after being properly served notice of the time, date, and place of the hearing. Pursuant to NRS 622A.350(2) and NRS 638.244(2), the Board adopted, as its Findings of Fact and Conclusions of Law, the allegations, averments, and legal conclusions stated in the Notice of Intended Action and Accusation on file herein. Those allegations, averments, and legal conclusions are restated below with minor conforming changes, as appropriate, to reflect the Board's determination to impose professional discipline in this case.

FINDINGS OF FACT

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Matthew Okeke, M.D. (Respondent), because Respondent, at the time of the violations alleged herein, held a Nevada controlled substance registration, Certificate of Registration No. CS10935.

2. Respondent is a physician licensed by the Nevada State Board of Medical Examiners to practice psychiatry in Nevada. During the time periods discussed herein, Respondent was a "practitioner" as that term is defined at NRS 453.126.

3. Between February 28, 2017, and November 21, 2018, Respondent maintained a psychiatric practice in Las Vegas, Nevada. During that time frame, while engaged at various times in overseas travel, Respondent issued or caused to be issued at least one hundred twenty (120)

prescriptions for controlled substances. These included prescriptions for alprazolam, clonazepam, diazepam, lacosamide, pregabalin, lisdexamfetamine, and buprenorphine.

4. Respondent was located outside of the United States during the periods from: 1) February 26 to March 11, 2017; 2) September 27 to October 2, 2017; 3) June 30 to July 17, 2018; and 4) November 9 to November 23, 2018.

5. While engaged in overseas travel as stated above, Respondent employed the following methods of issuing prescriptions for controlled substances: 1) Respondent pre-signed certain of the prescriptions and supplied then to persons under his supervision or control for subsequent distribution to consumers; 2) Respondent authorized or directed one or more persons under his supervision or control to issue prescriptions to consumers by affixing Respondent's signature to those prescriptions via a rubber stamp imprinted with Respondent's signature; and 3) Respondent authorized or directed one or more persons under his supervision or control to telephonically issue prescriptions for consumers using Respondent's name and controlled substances registration number.

6. During the periods described herein, Respondent intentionally failed to maintain patient treatment charts and/or records from which a person could reasonably determine whether Respondent had a bona fide therapeutic relationship with the persons to whom prescriptions for controlled substances were issued under Respondent's name and controlled substances registration number.

7. Respondent caused, directed, or permitted one or more persons under his supervision or control to issue prescriptions for controlled substances even though such person(s) were not licensed or registered under state or federal law to prescribe controlled substances. Respondent knew or should have known that such person(s) was not licensed or registered under state or federal law to prescribe controlled substances.

8. On or about March 9, 2020, the Nevada State Board of Medical Examiners disciplined Respondent for malpractice and for failure to maintain proper medical records.

9. On or about September 7, 2022, Respondent entered a guilty plea pursuant to a plea agreement of committing the offense of intentional failure to maintain adequate records, a gross misdemeanor violation of NRS 422.510(1).

10. On or about September 7, 2022, Discovery Mind Center Ltd. (Discovery Mind Center), a Nevada limited-liability company, entered a guilty plea pursuant to a plea agreement of submitting false claims to defraud Medicaid, a felony violation of NRS 422.540; and of using the identifying information of an older person for unlawful purposes, a felony violation of NRS 205.463.

11. At the time of the offenses described in paragraph 10 above, Respondent owned, controlled, and/or managed Discovery Mind Center. Respondent entered guilty pleas on behalf of Discovery Mind Center.

12. On or about December 8, 2022, the Nevada State Board of Medical Examiners disciplined Respondent for failure to maintain proper medical records.

13. On or about January 17, 2023, Respondent and Discovery Mind Center were sentenced for the criminal offenses described in paragraph 10 above. Discovery Mind Center was ordered to pay $330,000 in restitution, and Respondent was sentenced to probation and ordered to pay $300,000 in costs and penalties.

14. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was convicted pursuant to a plea agreement of one count of submitting false claims: Medicaid fraud, a category D felony in violation of NRS 422.540(1)(a) and NRS 422.540(2)(a), and one count of obtaining and using personal identifying information of an older person for unlawful purposes, a category D felony in violation of NRS 205.463(1) and NRS 205.463(3)(a).

15. At the time of the offenses described in paragraph 14 above, Respondent owned, controlled, and/or managed Matthew Okeke, M.D., Ltd., a Nevada limited-liability company. Respondent entered guilty pleas on behalf of the company.

16. On or about February 21, 2023, Matthew Okeke, M.D., Ltd., a Nevada limited-liability company, was sentenced for the offenses described in paragraph 14 above. The company was ordered to pay a fine of $100,000.00, among other fees and assessments.

17. Respondent was charged individually with the offenses described in paragraphs 9, 10, and 14 above. As noted above, Respondent entered into plea agreements whereby he avoided individual convictions for all offenses except the gross misdemeanor offense described in paragraph 9 above.

18. On or about October 25, 2022, Respondent submitted to the Board his application to renew his certificate of registration to prescribe controlled substances. The application specifically directed Respondent to disclose any charges, arrests, or convictions. Respondent disclosed the conviction described in paragraph 9 above, referring to it as a "misdemeanor for record keeping," but he omitted to disclose the individual charges and/or arrests related to the more serious offenses described in paragraphs 10 and 14 above.

CONCLUSIONS OF LAW

19. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. *See* NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. *See* NRS 453.056.

20. Every practitioner who prescribes controlled substances in Nevada must secure and maintain a certificate of registration from the Board. NRS 453.226(1)(a); NRS 453.231(3). A practitioner who fails to secure and maintain such a registration is subject to criminal and/or civil penalties for prescribing controlled substances without a registration. *See* NRS 453.232; NRS 453.553; NRS 453.5531.

21. In addition to any criminal or civil penalties that may apply, the Board may revoke or suspend the existing registration of any practitioner who has been guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the practitioner: 1) performs, without the required registration, any task or operation for which

registration is required; 2) performs his or her duties in an incompetent, unskillful, or negligent manner; 3) performs or engages in any fraudulent or deceitful transaction; or, 4) prescribes a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship. *See* NAC 639.945(1)(h)-(o).

23. Additionally, the Board may revoke or suspend the registration of any practitioner who has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to controlled substances, *see* NRS 639.210(11), or who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, *see* NRS 639.210(12).

24. Further, the Board may revoke or suspend the registration of any practitioner who has been convicted of a crime involving moral turpitude, dishonesty or corruption. *See* NRS 639.210(7)(c).

25. Finally, the Board may revoke or suspend the registration of any practitioner who "[h]as willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provisions of [NRS chapter 639]." *See* NRS 639.210(9).

26. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon such practitioner. The fine may not exceed $10,000 for each offense. *See* NRS 639.255(1)(f) and (3).

COUNT ONE

Failure to Comply with Federal Registration Requirements

27. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribed controlled substances in Nevada without their having obtained a registration from the Drug Enforcement Division of the U.S. Department of Justice. This constitutes a violation of federal law relating to controlled substances. *See* 21 U.S.C. 822(a)(2); 21 C.F.R. § 1306.03(a)(1). It also constitutes a violation of NRS 639.210(11), an offense for which the Board may impose administrative discipline.

COUNT TWO

Failure to Comply with State Registration Requirements

28. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada without their having obtained a registration from the Board. This violates state law relating to controlled substances. *See* NRS 453.321(1); NRS 453.226. It also constitutes a violation of NRS 639.210(12), an offense for which the Board may impose administrative discipline.

COUNT THREE

Participating in Deceitful Transactions

29. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada.

30. Respondent engaged in the conduct described herein as part of a scheme to bill Medicaid for services that Respondent did not provide. In this regard, Respondent used prescriptions to falsely document patient visits that never occurred.

31. By causing prescriptions to be issued in the manner described herein, Respondent engaged in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(h).

COUNT FOUR

Issuing Pre-signed Prescriptions

32. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances in Nevada by supplying patients with written prescriptions that Respondent had signed or stamped in advance of his overseas travel.

33. By causing prescriptions to be issued in the manner described herein, Respondent violated NRS 639.2353 by issuing pre-signed prescriptions. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 639.210(12). Through his conduct,

Respondent has potentially subjected other persons to administrative discipline. *See* NAC 639.295(15). (a physician assistant is subject to discipline for supplying patients with pre-signed prescriptions).

COUNT FIVE

Issuing Prescriptions from Unauthorized Locations

34. Between May 18, 2022, and January 22, 2023, while located outside the United States, Respondent caused prescriptions for controlled substances to be issued in his name and under his controlled substances registration number.

35. By engaging in the conduct described herein, Respondent prescribed controlled substances from locations other than his office and/or a location properly registered with the Board. This constitutes a violation of state law for which the Board may impose administrative discipline. *See* NRS 453.226; NRS 639.210(12); NAC 453.130(3).

COUNT SIX

Performing Duties in an Incompetent, Unskillful, or Negligent Manner

36. Respondent failed to maintain patient charts and records from which the Board and/or a member of the Board's staff could reasonably ascertain whether Respondent maintained bona fide therapeutic relationships with the persons to whom prescriptions for controlled substances were issued between May 18, 2022, and January 22, 2023. Pursuant to NRS 453.246 and NAC 639.945(1)(o), Respondent had a legal duty to maintain such records.

37. By failing to maintain records as required by NRS 453.246 and NAC 639.945(1)(o), Respondent violated state law relating to controlled substances and/or performed his duties in an incompetent, unskillful and/or negligent manner. This is a conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4) and (12); NAC 639.945(1)(i).

38. By subjecting persons under his supervision or control to potential disciplinary action, Respondent performed his duties in an incompetent, unskillful and/or negligent manner. This too is a conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Conviction of Crime Involving Dishonesty

39. As described herein, Respondent was convicted of a crime involving dishonesty. Respondent's conviction for intentional failure to maintain adequate records, a gross misdemeanor, was directly related to a fraudulent billing scheme involving the Discovery Mind Center and Matthew Okeke, M.D., Ltd., both limited-liability companies under the ownership and control of Respondent. The Board may impose administrative discipline based upon that conviction because the underlying offense involved dishonesty. *See* NRS 639.210(7)(c).

COUNT EIGHT
Prescribing Controlled Substances Without a Bona Fide Patient Relationship

40. Between February 28, 2017, and November 21, 2018, Respondent caused, directed, or assisted one or more persons under his supervision or control to prescribe controlled substances for persons whom Respondent identified as his patients. Respondent did not establish bona fide therapeutic relationship with one or more of these ostensible patients.

41. Respondent's conduct as described above constitutes unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(o).

ORDER

NOW, THEREFORE, based upon the above Findings of Fact and Conclusions of Law, the Board imposes upon Respondent Matthew Okeke, M.D., Certificate of Registration No. CS10935, the following professional discipline:

42. Respondent's Certificate of Registration No. CS10935 is hereby **REVOKED** pursuant to NRS 453.236 and NRS 453.241. Pursuant to NRS 622A.410(1) and NRS 639.257(1), Respondent may not petition the Board for reinstatement for a period of at least ten (10) years. Respondent may not prescribe controlled substances in the state of Nevada in any capacity unless the Board reinstates his certificate of registration.

43. Respondent shall pay an administrative fine in the amount of Two Thousand Five Hundred and No/100 Dollars ($2,500.00), payable to the State of Nevada, Office of the Treasurer.

44. Respondent shall reimburse the Board for its costs of investigation and prosecution in the amount of One Thousand Seven Hundred Fifty-Four and 68/100 Dollars ($1,754.68), payable to the Nevada State Board of Pharmacy.

45. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5) and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

46. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 17th day of January 2024.

Helen Park, President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Liborius Agwara, JD, PhD
Law Offices of Libo Agwara, LTD
2785 E. Desert Inn Road, Suite 280
Las Vegas, NV 89121

Matthew Okeke, MD
[redacted] S. Las Vegas Blvd., [redacted]
Las Vegas, NV 89101

Darlene Nases
DARLENE NASES

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **PETITION FOR RECONSIDERATION**

COMES NOW, Respondent Matthew Okeke, M.D., by and through his counsel, Liborius Agwara, Esq., of the Law Offices of Libo Agwara, Ltd., and hereby files his Petition For Reconsideration of the Board's Findings Of Fact, Conclusions Of Law, and Order, which was entered by the Board on January 27, 2024.

This Petition is made and based on the attached Declaration of Liborius Agwara, Esq., counsel for Respondent.

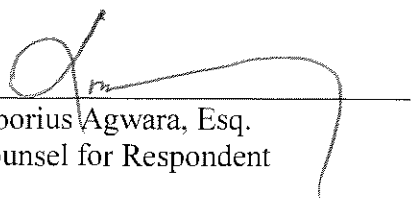
Starting in or about September 2023 and through the end of November 2023, Senior General Counsel for the Board, Gregory Zunino, Esq., and Respondent's counsel, Liborius Agwara, Esq., engaged in a series of negotiations and were able to arrive at a resolution. The first draft of the settlement agreement, which Respondent and his counsel signed on November 17, 2023, is attached hereto as Exhibit "A." Thereafter, the parties realized that Respondent's inactive status with the medical board meant that some of the provisions in the first draft would have to be changed. The parties were able to agree on the terms of the final draft, a copy of which is attached hereto as Exhibit "B." Counsel for Respondent signed the final draft the

settlement agreement before leaving for Africa, where he runs a foundation, on December 17, 2023. See Exhibit "C." Respondent subsequently came to counsel's office and signed the final draft on December 20, 2023, and left the signed copy with counsel's staff, who were supposed to have scanned and emailed the signed copy to Mr. Zunino. For reasons that no one can explain, counsel's staff put the signed copy in a different file belonging to Respondent, without first scanning and emailing it to Mr. Zunino. Counsel returned to the United States on January 17, 2024. See Exhibit "D." Thinking that Mr. Zunino had been sent the signed agreement, counsel was awaiting a notice of hearing by the board, wherein the settlement agreement would be presented for acceptance, but was shocked when he received, by certified mail, a copy of the board's findings of fact, conclusions of law, and order on January 29, 2024.

Respondent did not ignore this matter, as there were numerous emails between Mr. Zunino and counsel. Indeed, the parties' negotiations were going so well that counsel for both parties did not see the need for Respondent to file an Answer to the Complaint, as they were confident the matter would be resolved.

In light of the foregoing, Respondent respectfully requests that the Board grant his Petion for Reconsideration.

Dated this 31st day of January 2024.



Liborius Agwara, Esq.
Counsel for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S**

RESPONDENT'S COUNSEL'S DECLARATION IN SUPPORT OF PETITION FOR RECONSIDERATION

I, LIBORIUS AGWARA, ESQ., counsel for Respondent Matthew Okeke, M.D., under the penalty of perjury, hereby declare:

1. That I am an attorney licensed to practice in the State of Nevada.

2. That I represent Dr. Matthew Okeke, Respondent in this matter.

3. That between the months of September 2023 and November 2023, Senior General Counsel for the Board, Mr. Zunino, and I, engaged in a series of negotiations and arrived at an acceptable settlement agreement on behalf of the Board and Respondent.

4. That the first draft, which was signed by Respondent and me, had to be revised due to the fact that Respondent's medical license was inactive at the time.

5. That I signed the final settlement agreement before leaving for Africa on December 17, 2023, while Respondent signed it on December 20, 2023; that my staff misplaced the signed agreement by putting it in another file belonging to the Respondent, without first sending it to Mr. Zunino.

6. That this matter was resolved by the parties and would not have gone to a hearing, if it had not been for my staff's mistake; that I take full responsibility for my staff's mistake and hope that the Board does not punish Respondent for my office's mistake.

FURTHER YOUR DECLARANT SAYETH NAUGHT.

Dated this 31st day of January 2024.

Liborius Agwara, Esq.
Counsel for Respondent

EXHIBIT "A"

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. MATTHEW OKEKE, M.D., Certificate of Registration No. CS10935, Respondent.	Case No. 19-013-CS-A STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Matthew Okeke, M.D., ("Respondent"), by and through his counsel, Liborius Agwara, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the First Amended Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation, and that he has executed it knowingly and voluntarily.

4. Respondent acknowledges that he is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with its provisions, Respondent

hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree as follows:

A. Respondent, a physician, holds Certificate of Registration No. CS10935, which was originally issued by the Board in 2016. Certificate of Registration No. CS10935 authorizes Respondent to prescribe controlled substances in Nevada.

B. Respondent is licensed by the Nevada Board of Medical Examiners ("BME") to practice medicine in Nevada; however, in Case No. 21-22461-1, the BME placed conditions upon Respondent's medical license requiring Respondent to successfully complete a 24-month period of probation in connection with the BME's Case No. 21-22461-1. Respondent's period of probation with the BME commenced on December 8, 2022.

C. In addition to having agreed to the terms and conditions of the probation imposed by the BME in Case No. 21-22461-1, Respondent placed his medical license on inactive status with the BME.

D. Respondent understands and acknowledges that pursuant to the Board's administrative regulation, LCB File No. R071-91 (February 7, 2020), Certificate of Registration No. CS10935 will be placed on inactive status until such time as Respondent petitions the Board to reactivate it.

E. As of the effective date of this Order, in addition to being placed in inactive status, Certificate of Registration No. CS10935 shall be **SUSPENDED** until December 31, 2024; however, the execution of said order of suspension shall be stayed pending Respondent's completion of a period of probation ending December 31, 2024. During this period of probation, Respondent must: 1) comply with all Nevada laws relating to dangerous drugs and controlled substances; 2) successfully

complete the terms and conditions of the probation imposed by the BME in connection with Case No. 21-22401-1; 3) place his Nevada medical license on active status before engaging in the practice of medicine in Nevada; and 4) petition the Board to place Certificate of Registration No. CS29711 on active status before prescribing any dangerous drugs or controlled substances in Nevada.

F. Further, Respondent shall pay an administrative fine in the amount of Two Thousand Five Hundred and 00/100 Dollars ($2,500.00); and Respondent shall partially reimburse the Board in the amount of One Thousand and 00/100 Dollars ($1,000.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter.

8. Failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may unconditionally suspend or revoke Certificate of Registration No. CS10935 and/or impose additional discipline not inconsistent with the provisions of NRS Chapters 453 and 639. In the absence of such a finding of a violation, and assuming Respondent renews CS10935 when it comes due for renewal, Respondent's authority to prescribe controlled substances in Nevada shall be automatically restored without probationary conditions or restrictions effective December 5, 2024.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on December 6, 2023, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 19-013-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of December 2023.

Helen Park, President
Nevada State Board of Pharmacy

contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Upon approval of this Stipulation by the Board, Respondent shall pay the administrative fine agreed to herein by *check* or *money order* payable to "**State of Nevada, Office of the Treasurer**." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by February 1, 2024.

13. Upon approval of this Stipulation by the Board, Respondent shall pay the costs and fees agreed to herein by *check* or *money order* payable to "**Nevada State Board of Pharmacy**." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by February 1, 2024.

14. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

AGREED:

Signed this 17th day of November 2023.

MATTHEW OKEKE, M.D.

Signed this 17th day of November 2023.

NEVADA STATE BOARD OF PHARMACY

By_____
GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

Liborius Agwara, Esq.
Nevada Bar No. 7576
Attorney for Respondent Matthew Okeke, M.D.

EXHIBIT "B"

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW OKEKE, M.D.,** **Certificate of Registration No. CS10935,** **Respondent.**	**Case No. 19-013-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Matthew Okeke, M.D., ("Respondent"), by and through his counsel, Liborius Agwara, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the First Amended Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that he understands the terms of this Stipulation, and that he has executed it knowingly and voluntarily.

4. Respondent acknowledges that he is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with its provisions, Respondent

hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree as follows:

A. As of the effective date of this Order, Respondent's Certificate of Registration No. CS10935 shall be **SUSPENDED** for a period of two (2) years. Respondent understands and acknowledges that during this two-year period of suspension, Respondent will have no authority to prescribe controlled substances in Nevada and will be ineligible to renew Certificate of Registration No. CS10935 when it would otherwise come due for renewal on October 31, 2024. Further, at the expiration of the two-year period of suspension, Respondent must reapply to the Board for a new certificate of registration if Respondent intends to prescribe controlled substances in Nevada.

B. During the two-year period of suspension referenced above, Respondent shall comply with all laws and regulations governing the practice of medicine in any jurisdiction in which Respondent holds a professional license or registration.

C. During the two-year period of suspension referenced above, Respondent shall refrain from engaging in any conduct that results in a criminal conviction, whether for a felony or a misdemeanor, under any federal, state, or local law.

D. On or before May 1, 2024, Respondent shall pay an administrative fine in the amount of Two Thousand Five Hundred and 00/100 Dollars ($2,500.00), payable by *certified check* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

E. On or before May 1, 2024, Respondent shall partially reimburse the Board in the amount of One Thousand and 00/100 Dollars ($1,000.00) for recoverable attorney's fees and costs

incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check* or *money order* written to the "**Nevada State Board of Pharmacy.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

8. Respondent understands and acknowledges that the Board has already entered a decision dated January 17, 2024, in which the Board imposed discipline upon Respondent for the charges stated in the Accusation, including an order revoking Certificate of Registration No. CS10935 for a period of ten (10) years. Respondent has petitioned the Board for reconsideration of the Board's decision dated January 17, 2024, requesting that the Board vacate its decision dated January 17, 2024. Respondent's counsel and the Board's Senior General Counsel will jointly recommend that the Board vacate its decision dated January 17, 2024. However, Respondent has been advised and understands that the Board may not accept this recommendation.

9. If the Board agrees to vacate its decision dated January 17, 2024, the Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent fails to appear for the meeting.

10. If the Board agrees to vacate its decision dated January 17, 2024, the Board may subsequently approve this Stipulation in settlement of the charges stated in the Accusation. However, Respondent understands and acknowledges that even if the Board agrees to vacate its decision dated January 17, 2024, the Board is not obligated to accept this Stipulation. Assuming the Board accepts this Stipulation, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board accepts this Stipulation, failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may, pursuant

to NRS 622A.410(1), revoke Certificate of Registration No. CS10935 for a period of not more than ten (10) years.

12. If the Board agrees to vacate its decision dated January 17, 2024, but rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

AGREED:

Signed this 9th day of February 2024.

MATTHEW OKEKE, M.D.

Signed this 12th day of February 2024.

NEVADA STATE BOARD OF PHARMACY

By
GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

Liborius Agwara, Esq.
Nevada Bar No. 7576
Attorney for Respondent Matthew Okeke, M.D.

DECISION AND ORDER

Having previously vacated its decision dated January 17, 2024, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 19-013-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of March 2024.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **and,** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondents.**	**CASE NOS. 22-053-PH-S** **22-053-RPH-A-S** **22-053-RPH-B-S** **22-053-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent DVH Hospital Alliance, LLC ("Respondent DVH"), because Respondent DVH is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent DVH holds pharmacy license number PH02587.

2. The Board has personal jurisdiction over Respondent Elliott Asarch ("Respondent Asarch") because Respondent Asarch is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Asarch holds certificate of registration no. 19265.

3. The Board has personal jurisdiction over Respondent Matthew Huntington ("Respondent Huntington") because Respondent Huntington is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Huntington holds certificate of registration no. 18203.

4. The Board has personal jurisdiction over Respondent Marissa Crain ("PT Crain") because PT Crain was formerly registered by the Board to work as a pharmacy technician. The allegations below relate to PT Crain's employment as a pharmacy technician between December 2019 and February 2022. PT Crain held certificate of registration no. PT14524, which expired on October 31, 2022.

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations pertaining to the possession, control, and distribution of dangerous drugs and controlled substances.

FACTUAL ALLEGATIONS

6. At all times relevant to this accusation, Respondent DVH operated a pharmacy within the Desert View Hospital ("DVH Hospital"), located at 360 South Lola Lane in Pahrump, Nevada.

7. Between October 28, 2019, and February 18, 2022, Respondent DVH employed PT Crain as a pharmacy technician.

8. During her employment with Respondent DVH, PT Crain stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.

9. In February 2022, PT Crain admitted to stealing controlled substances from DVH Hospital. Respondent DVH thereafter terminated PT Crain's employment at DVH Hospital. In September 2022, PT Crain pleaded guilty to felony charges of unlawful possession of a controlled substance and embezzlement.

10. Between November 13, 2020, and October 5, 2021, Respondent DVH employed Respondent Asarch as its managing pharmacist. During this time frame, while under Respondent Asarch's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

11. Between October 6, 2021, and February 18, 2022, Respondent DVH employed Respondent Huntington as its managing pharmacist. During this time frame, while under Respondent Huntington's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

12. At all times relevant to this accusation, Respondent DVH owned or leased a Pyxis automated medication dispensing system. Respondent DVH used the Pyxis system to store and dispense dangerous drugs and controlled substances.

13. The Pyxis system consisted of a Pyxis CII safe, which was located in the pharmacy of the DVH Hospital. The Pyxis system also consisted of Pyxis MedStations, which were located at different places outside the pharmacy but inside the DVH Hospital where designated medical practitioners had access to them.

14. The Pyxis CII safe served as the central vault for storing dangerous drugs and controlled substances in the hospital pharmacy. The Pyxis MedStations served as automated dispensing devices from which medical practitioners removed dangerous drugs and controlled substances for administering to patients of the DVH Hospital.

15. The Pyxis system is equipped with digital technology that tracks dangerous drugs and controlled substances when they are removed from the Pyxis CII safe and then transferred to the Pyxis MedStations. The system also tracks removals from and/or deposits to the Pyxis MedStations. The Pyxis system is capable of generating a report that identifies in real time all such transactions involving dangerous drugs and controlled substances. If used properly, the Pyxis system provides the means by which a hospital pharmacy can maintain a perpetual inventory of controlled substances.

16. During her employment at DVH Hospital, PT Crain was responsible for restocking the Pyxis MedStations. This required her to remove dangerous drugs and controlled substances from the Pyxis CII safe and then transport them to the Pyxis MedStations.

17. While performing her restocking duties, PT Crain frequently worked without supervision. PT Crain was rarely if ever accompanied by another hospital employee when she removed inventory from the Pyxis CII safe and/or transported it to the Pyxis MedStations.

18. While performing her restocking duties, PT Crain often pretended to restock the Pyxis MedStations with inventory removed from the Pyxis CII safe. In fact, PT Crain stole much of the inventory that she removed from the Pyxis CII safe, never transferring it to the Pyxis MedStations and/or never returning it to the Pyxis CII safe.

19. During his tenure as managing pharmacist at DVH Hospital, Respondent Asarch neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

20. During his tenure as managing pharmacist at DVH Hospital, Respondent Huntington neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Instead, Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

21. In February 2022, Board Inspector Luis Curras met with Respondent Huntington to discuss some deficiencies that were noted during a previous inspection of the hospital pharmacy. During that meeting, Inspector Curras explained the technology described in paragraph 15 above. Respondent Huntington thereafter generated a report using the technology. Based on the report,

Respondent Huntington determined that PT Crain had been stealing controlled substances from the Pyxis CII safe.

APPLICABLE LAW

22. Every pharmacy in Nevada must be licensed by the Board to dispense dangerous drugs and/or controlled substances. NRS 639.230; NRS 639.231.

23. Additionally, every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

24. A "managing pharmacist" is a registered pharmacist who is responsible for managing the operation of the pharmacy. NRS 639.0087. This includes the duty to supervise the procurement and storage of drugs in the pharmacy. NAC 639.473(1).

25. The managing pharmacist must establish policies, procedures and systems related to the procurement and storage of drugs, the distribution of drugs to be administered to patients, and the recording of all transactions of the pharmacy required by applicable state and federal laws. NAC 639.468(4), (6) and (9).

26. A pharmacy must maintain records for controlled substances in a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy. NAC 639.485(1)(b). Additionally, a pharmacy must maintain a perpetual inventory of any controlled substance listed in schedule II. NAC 639.485(2).

27. The Board may revoke or suspend the license of any pharmacy owner, pharmacist, or pharmacy technician who has violated any Nevada law or regulation relating to the practice of pharmacy, or who has been convicted of a felony relating to the practice of pharmacy. NRS 639.210(7) & (12); NRS 639.230(5).

28. The Board may revoke or suspend the license of a managing pharmacist who has violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides. NRS 639.210(15)

29. The Board may revoke or suspend the license of a pharmacist upon finding that the pharmacist committed unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.230(5).

30. A pharmacist commits unprofessional conduct when the pharmacist performs their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

31. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d).

32. Pharmacy managers and/or pharmacists are responsible for the acts and/or omissions of the pharmacy employees under their supervision if they knew or should have known of such acts and/or omissions. NAC 639.702. Further, pharmacy owners are responsible for the acts and/or omissions of pharmacy employees regardless of whether they knew or should have known of such acts and/or omissions. NRS 639.230(5); NAC 639.945(2),

33. In addition to or in lieu of revoking or suspending a license or certificate of registration, the Board may impose an administrative fine upon the offending pharmacy or pharmacist. The fine may not exceed $10,000 for each offense. NRS 639.255(3).

COUNT ONE

Unlawful Diversion of Controlled Substances

34. Between October 28, 2019, and February 18, 2022, PT Crain knowingly or intentionally acquired or obtained possession of controlled substances by means of deception and/or subterfuge, in violation of NRS 453.331(1)(d).

35. For her criminal misconduct as alleged above, PT Crain is subject to discipline by the Board pursuant to NRS 639.210(7) and/or (12).

36. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for PT Crain's unlawful diversion of controlled substances. NRS 453.331(1)(d), NRS 639.230(5), and NAC 639.945(2).

37. Respondent Asarch is subject to discipline by the Board because Respondent Asarch knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

38. Respondent Huntington is subject to discipline by the Board because Respondent Huntington knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

COUNT TWO
Failure by Managing Pharmacist to Comply with NAC 639.485

39. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Asarch familiarized himself with the technology described in paragraph 15 above, Respondent Asarch could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

40. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Huntington familiarized himself with the technology described in paragraph 15 above, Respondent Huntington could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

41. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(15).

42. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(15).

43. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the noncompliance with NAC 639.485(2) as alleged above. NRS 639.230(5); NAC 639.945(2).

COUNT THREE
Unprofessional Conduct by a Pharmacist

44. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 11 months.

45. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of dangerous drugs and controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 6 months.

46. As the managing pharmacist for Respondent DVH, Respondent Asarch had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Asarch breached this duty.

47. As the managing pharmacist for Respondent DVH, Respondent Huntington had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Huntington breached this duty.

48. As alleged above, Respondent Asarch performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(4).

49. As alleged above, Respondent Huntington performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(4).

50. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the unprofessional conduct as alleged above. NRS 639.230(5); NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to the pharmacy license of Respondent DVH and the certificates of registration of PT Crain, Respondent Asarch, and Respondent Huntington.

DATED this 9th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **Respondent.**	**CASE NO. 22-053-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **Respondent.**	**CASE NO. 22-053-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR DVH HOSPITAL ALLIANCE, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of January, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

DVH Hospital Alliance, LLC
360 S. Lola Ln.
Pahrump, NV 89048

Elliott Asarch, RPH
[redacted] Reyes Ave.
Las Vegas, NV 89141

Matthew Huntington, RPH
[redacted] Orduno St.
Las Vegas, NV 89161

Marissa Crain, PT
[redacted] Red Rock Dr
Pahrump, NV 89048

Thomas Gibson, Esq.
1601 E. Basin Ave., Ste #302
Pahrump, NV 89060

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DVH HOSPITAL ALLIANCE, LLC, License No. IB02134, and MATTHEW HUNTINGTON, RPH, Certificate of Registration No. 18203, Respondents.	Case Nos. 22-053-PH-S 22-053-RPH-B-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondents DVH Hospital Alliance, LLC, and Matthew Huntington (together "Respondents"), by and through counsel, Maria Nutile, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondents and this matter.

2. The Board's staff properly served Respondents with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondents acknowledge that after having consulted with counsel, they understand the terms of this Stipulation, and that they have executed it knowingly and voluntarily.

4. Respondents acknowledge that they are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondents under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondents have failed to comply with its provisions,

Respondents hereby freely and voluntarily waive the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondents admit that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged against each of them in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent DVH Hospital Alliance, LLC ("Respondent DVH") agree to the following:

A. In lieu of risking a possible suspension or revocation of its pharmacy license by proceeding with a hearing on the merits, Respondent DVH agrees to submit to four quarterly inspections of its pharmacy within the Desert View Hospital, located at 360 South Lola Lane in Pahrump, Nevada. These inspections will be conducted by the Board's inspectors for the calendar quarters ending June 30, 2024, September 30, 2024, December 31, 2024, and March 31, 2025, or at such other quarterly intervals as the parties may agree.

B. Respondent DVH further agrees that its registered pharmacists will maintain a perpetual inventory of all controlled substances in stock in the pharmacy; that they will supply the Board's inspectors with copies of the pharmacy's most current policies and procedures to reflect the maintenance of a perpetual inventory for all controlled substances; that they will supply the Board's inspectors with copies of the pharmacy's most current policies and procedures concerning the investigation and reporting of suspected controlled substance losses; and that they will make reasonable updates to policies and procedures as the Board's inspectors may recommend.

C. On or before May 1, 2024, Respondent DVH shall pay an administrative fine in the amount of Ten Thousand and 00/100 Dollars ($10,000.00), payable by *certified check, cashier's check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

D. On or before May 1, 2024, Respondent DVH shall partially reimburse the Board in the amount of One Thousand and 00/100 Dollars ($1,000.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check, cashier's check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent Matthew Huntington ("Respondent Huntington") agree to the following:

A. As of the effective date of this Order, Respondent Huntington's Certificate of Registration No. 18203 shall be **SUSPENDED** for a period of one (1) year; however, the execution of the suspension shall be stayed, and Respondent Huntington shall be authorized to engage in the practice of pharmacy in Nevada provided that Respondent Huntington satisfies the terms and conditions stated below.

B. Respondent Huntington shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs.

C. Respondent Huntington shall, as long as he remains employed by Respondent DVH as the managing pharmacist at the Desert View Hospital, facilitate the performance by Respondent DVH of its responsibilities as described above.

D. On or before May 1, 2024, Respondent Huntington shall pay an administrative fine in the amount of Two Thousand Five Hundred and 00/100 Dollars ($2,500.00), payable by *certified check, cashier's check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

E. On or before May 1, 2024, Respondent Huntington shall partially reimburse the Board in the amount of Five Hundred and 00/100 Dollars ($500.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check,*

cashier's check, or *money order* written to the "**Nevada State Board of Pharmacy.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondents or their attorney fail to appear for the meeting.

10. Respondents understand and acknowledge that the Board is not obligated to accept this Stipulation. Assuming the Board accepts this Stipulation, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board accepts this Stipulation, failure by Respondents to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondents, or either of them as applicable, to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may, pursuant to NRS 622A.410(1), impose additional discipline not inconsistent with the provisions of NRS chapter 639.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation.

[Remainder of this Page Left Blank]

AGREED:

Signed this 9th day of February 2024.

MATTHEW HUNTINGTON, RPH
Certificate of Registration No. 18203

DVH HOSPITAL ALLIANCE, LLC
Pharmacy License No. IB02134

By _____
Print Susan K. Davila
Title CEO

Signed this 9th day of February 2024.

NEVADA STATE BOARD OF PHARMACY

By _____
GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

_____
Maria Nutile, Esq.
Nevada Bar No. 7847
Attorney for Respondents

DECISION AND ORDER

As to Respondent DVH Hospital Alliance, LLC, and Respondent Matthew Huntington, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 23-053-PH-S and Case No. 25-053-RPH-B-S, respectively, and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of March 2024.

_____
Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **and,** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondents.**	**CASE NOS. 22-053-PH-S** **22-053-RPH-A-S** **22-053-RPH-B-S** **22-053-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent DVH Hospital Alliance, LLC ("Respondent DVH"), because Respondent DVH is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent DVH holds pharmacy license number PH02587.

2. The Board has personal jurisdiction over Respondent Elliott Asarch ("Respondent Asarch") because Respondent Asarch is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Asarch holds certificate of registration no. 19265.

3. The Board has personal jurisdiction over Respondent Matthew Huntington ("Respondent Huntington") because Respondent Huntington is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Huntington holds certificate of registration no. 18203.

4. The Board has personal jurisdiction over Respondent Marissa Crain ("PT Crain") because PT Crain was formerly registered by the Board to work as a pharmacy technician. The allegations below relate to PT Crain's employment as a pharmacy technician between December 2019 and February 2022. PT Crain held certificate of registration no. PT14524, which expired on October 31, 2022.

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations pertaining to the possession, control, and distribution of dangerous drugs and controlled substances.

FACTUAL ALLEGATIONS

6. At all times relevant to this accusation, Respondent DVH operated a pharmacy within the Desert View Hospital ("DVH Hospital"), located at 360 South Lola Lane in Pahrump, Nevada.

7. Between October 28, 2019, and February 18, 2022, Respondent DVH employed PT Crain as a pharmacy technician.

8. During her employment with Respondent DVH, PT Crain stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.

9. In February 2022, PT Crain admitted to stealing controlled substances from DVH Hospital. Respondent DVH thereafter terminated PT Crain's employment at DVH Hospital. In September 2022, PT Crain pleaded guilty to felony charges of unlawful possession of a controlled substance and embezzlement.

10. Between November 13, 2020, and October 5, 2021, Respondent DVH employed Respondent Asarch as its managing pharmacist. During this time frame, while under Respondent Asarch's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

11. Between October 6, 2021, and February 18, 2022, Respondent DVH employed Respondent Huntington as its managing pharmacist. During this time frame, while under Respondent Huntington's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

12. At all times relevant to this accusation, Respondent DVH owned or leased a Pyxis automated medication dispensing system. Respondent DVH used the Pyxis system to store and dispense dangerous drugs and controlled substances.

13. The Pyxis system consisted of a Pyxis CII safe, which was located in the pharmacy of the DVH Hospital. The Pyxis system also consisted of Pyxis MedStations, which were located at different places outside the pharmacy but inside the DVH Hospital where designated medical practitioners had access to them.

14. The Pyxis CII safe served as the central vault for storing dangerous drugs and controlled substances in the hospital pharmacy. The Pyxis MedStations served as automated dispensing devices from which medical practitioners removed dangerous drugs and controlled substances for administering to patients of the DVH Hospital.

15. The Pyxis system is equipped with digital technology that tracks dangerous drugs and controlled substances when they are removed from the Pyxis CII safe and then transferred to the Pyxis MedStations. The system also tracks removals from and/or deposits to the Pyxis MedStations. The Pyxis system is capable of generating a report that identifies in real time all such transactions involving dangerous drugs and controlled substances. If used properly, the Pyxis system provides the means by which a hospital pharmacy can maintain a perpetual inventory of controlled substances.

16. During her employment at DVH Hospital, PT Crain was responsible for restocking the Pyxis MedStations. This required her to remove dangerous drugs and controlled substances from the Pyxis CII safe and then transport them to the Pyxis MedStations.

17. While performing her restocking duties, PT Crain frequently worked without supervision. PT Crain was rarely if ever accompanied by another hospital employee when she removed inventory from the Pyxis CII safe and/or transported it to the Pyxis MedStations.

18. While performing her restocking duties, PT Crain often pretended to restock the Pyxis MedStations with inventory removed from the Pyxis CII safe. In fact, PT Crain stole much of the inventory that she removed from the Pyxis CII safe, never transferring it to the Pyxis MedStations and/or never returning it to the Pyxis CII safe.

19. During his tenure as managing pharmacist at DVH Hospital, Respondent Asarch neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

20. During his tenure as managing pharmacist at DVH Hospital, Respondent Huntington neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Instead, Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

21. In February 2022, Board Inspector Luis Curras met with Respondent Huntington to discuss some deficiencies that were noted during a previous inspection of the hospital pharmacy. During that meeting, Inspector Curras explained the technology described in paragraph 15 above. Respondent Huntington thereafter generated a report using the technology. Based on the report,

Respondent Huntington determined that PT Crain had been stealing controlled substances from the Pyxis CII safe.

APPLICABLE LAW

22. Every pharmacy in Nevada must be licensed by the Board to dispense dangerous drugs and/or controlled substances. NRS 639.230; NRS 639.231.

23. Additionally, every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

24. A "managing pharmacist" is a registered pharmacist who is responsible for managing the operation of the pharmacy. NRS 639.0087. This includes the duty to supervise the procurement and storage of drugs in the pharmacy. NAC 639.473(1).

25. The managing pharmacist must establish policies, procedures and systems related to the procurement and storage of drugs, the distribution of drugs to be administered to patients, and the recording of all transactions of the pharmacy required by applicable state and federal laws. NAC 639.468(4), (6) and (9).

26. A pharmacy must maintain records for controlled substances in a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy. NAC 639.485(1)(b). Additionally, a pharmacy must maintain a perpetual inventory of any controlled substance listed in schedule II. NAC 639.485(2).

27. The Board may revoke or suspend the license of any pharmacy owner, pharmacist, or pharmacy technician who has violated any Nevada law or regulation relating to the practice of pharmacy, or who has been convicted of a felony relating to the practice of pharmacy. NRS 639.210(7) & (12); NRS 639.230(5).

28. The Board may revoke or suspend the license of a managing pharmacist who has violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides. NRS 639.210(15)

29. The Board may revoke or suspend the license of a pharmacist upon finding that the pharmacist committed unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.230(5).

30. A pharmacist commits unprofessional conduct when the pharmacist performs their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

31. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d).

32. Pharmacy managers and/or pharmacists are responsible for the acts and/or omissions of the pharmacy employees under their supervision if they knew or should have known of such acts and/or omissions. NAC 639.702. Further, pharmacy owners are responsible for the acts and/or omissions of pharmacy employees regardless of whether they knew or should have known of such acts and/or omissions. NRS 639.230(5); NAC 639.945(2),

33. In addition to or in lieu of revoking or suspending a license or certificate of registration, the Board may impose an administrative fine upon the offending pharmacy or pharmacist. The fine may not exceed $10,000 for each offense. NRS 639.255(3).

COUNT ONE
Unlawful Diversion of Controlled Substances

34. Between October 28, 2019, and February 18, 2022, PT Crain knowingly or intentionally acquired or obtained possession of controlled substances by means of deception and/or subterfuge, in violation of NRS 453.331(1)(d).

35. For her criminal misconduct as alleged above, PT Crain is subject to discipline by the Board pursuant to NRS 639.210(7) and/or (12).

36. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for PT Crain's unlawful diversion of controlled substances. NRS 453.331(1)(d), NRS 639.230(5), and NAC 639.945(2).

37. Respondent Asarch is subject to discipline by the Board because Respondent Asarch knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

38. Respondent Huntington is subject to discipline by the Board because Respondent Huntington knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

COUNT TWO
Failure by Managing Pharmacist to Comply with NAC 639.485

39. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Asarch familiarized himself with the technology described in paragraph 15 above, Respondent Asarch could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

40. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Huntington familiarized himself with the technology described in paragraph 15 above, Respondent Huntington could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

41. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(15).

42. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(15).

43. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the noncompliance with NAC 639.485(2) as alleged above. NRS 639.230(5); NAC 639.945(2).

COUNT THREE
Unprofessional Conduct by a Pharmacist

44. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 11 months.

45. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of dangerous drugs and controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 6 months.

46. As the managing pharmacist for Respondent DVH, Respondent Asarch had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Asarch breached this duty.

47. As the managing pharmacist for Respondent DVH, Respondent Huntington had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Huntington breached this duty.

48. As alleged above, Respondent Asarch performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(4).

49. As alleged above, Respondent Huntington performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(4).

50. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the unprofessional conduct as alleged above. NRS 639.230(5); NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to the pharmacy license of Respondent DVH and the certificates of registration of PT Crain, Respondent Asarch, and Respondent Huntington.

DATED this 9th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondent.**	**CASE NO. 22-053-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondent.**	**CASE NO. 22-053-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MARISSA CRAIN, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of January, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

DVH Hospital Alliance, LLC
360 S. Lola Ln.
Pahrump, NV 89048

Elliott Asarch, RPH
[redacted] Reyes Ave.
Las Vegas, NV 89141

Matthew Huntington, RPH
[redacted] Orduno St.
Las Vegas, NV 89161

Marissa Crain, PT
[redacted] Red Rock Dr
Pahrump, NV 89048

Thomas Gibson, Esq.
1601 E. Basin Ave., Ste #302
Pahrump, NV 89060

SHIRLEY HUNTING

FILED
JAN 29 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondent.**	**CASE NO. 22-053-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

NONE

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

NONE

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 26TH day of JANUARY, 2024.

MARISSA CRAIN, PT

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FILED
JAN 0 9 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **and,** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondents.**	**CASE NOS. 22-053-PH-S** **22-053-RPH-A-S** **22-053-RPH-B-S** **22-053-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent DVH Hospital Alliance, LLC ("Respondent DVH"), because Respondent DVH is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent DVH holds pharmacy license number PH02587.

2. The Board has personal jurisdiction over Respondent Elliott Asarch ("Respondent Asarch") because Respondent Asarch is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Asarch holds certificate of registration no. 19265.

3. The Board has personal jurisdiction over Respondent Matthew Huntington ("Respondent Huntington") because Respondent Huntington is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Huntington holds certificate of registration no. 18203.

4. The Board has personal jurisdiction over Respondent Marissa Crain ("PT Crain") because PT Crain was formerly registered by the Board to work as a pharmacy technician. The allegations below relate to PT Crain's employment as a pharmacy technician between December 2019 and February 2022. PT Crain held certificate of registration no. PT14524, which expired on October 31, 2022.

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations pertaining to the possession, control, and distribution of dangerous drugs and controlled substances.

FACTUAL ALLEGATIONS

6. At all times relevant to this accusation, Respondent DVH operated a pharmacy within the Desert View Hospital ("DVH Hospital"), located at 360 South Lola Lane in Pahrump, Nevada.

7. Between October 28, 2019, and February 18, 2022, Respondent DVH employed PT Crain as a pharmacy technician.

8. During her employment with Respondent DVH, PT Crain stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.

9. In February 2022, PT Crain admitted to stealing controlled substances from DVH Hospital. Respondent DVH thereafter terminated PT Crain's employment at DVH Hospital. In September 2022, PT Crain pleaded guilty to felony charges of unlawful possession of a controlled substance and embezzlement.

10. Between November 13, 2020, and October 5, 2021, Respondent DVH employed Respondent Asarch as its managing pharmacist. During this time frame, while under Respondent Asarch's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

11. Between October 6, 2021, and February 18, 2022, Respondent DVH employed Respondent Huntington as its managing pharmacist. During this time frame, while under Respondent Huntington's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

12. At all times relevant to this accusation, Respondent DVH owned or leased a Pyxis automated medication dispensing system. Respondent DVH used the Pyxis system to store and dispense dangerous drugs and controlled substances.

13. The Pyxis system consisted of a Pyxis CII safe, which was located in the pharmacy of the DVH Hospital. The Pyxis system also consisted of Pyxis MedStations, which were located at different places outside the pharmacy but inside the DVH Hospital where designated medical practitioners had access to them.

14. The Pyxis CII safe served as the central vault for storing dangerous drugs and controlled substances in the hospital pharmacy. The Pyxis MedStations served as automated dispensing devices from which medical practitioners removed dangerous drugs and controlled substances for administering to patients of the DVH Hospital.

15. The Pyxis system is equipped with digital technology that tracks dangerous drugs and controlled substances when they are removed from the Pyxis CII safe and then transferred to the Pyxis MedStations. The system also tracks removals from and/or deposits to the Pyxis MedStations. The Pyxis system is capable of generating a report that identifies in real time all such transactions involving dangerous drugs and controlled substances. If used properly, the Pyxis system provides the means by which a hospital pharmacy can maintain a perpetual inventory of controlled substances.

16. During her employment at DVH Hospital, PT Crain was responsible for restocking the Pyxis MedStations. This required her to remove dangerous drugs and controlled substances from the Pyxis CII safe and then transport them to the Pyxis MedStations.

17. While performing her restocking duties, PT Crain frequently worked without supervision. PT Crain was rarely if ever accompanied by another hospital employee when she removed inventory from the Pyxis CII safe and/or transported it to the Pyxis MedStations.

18. While performing her restocking duties, PT Crain often pretended to restock the Pyxis MedStations with inventory removed from the Pyxis CII safe. In fact, PT Crain stole much of the inventory that she removed from the Pyxis CII safe, never transferring it to the Pyxis MedStations and/or never returning it to the Pyxis CII safe.

19. During his tenure as managing pharmacist at DVH Hospital, Respondent Asarch neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

20. During his tenure as managing pharmacist at DVH Hospital, Respondent Huntington neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Instead, Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

21. In February 2022, Board Inspector Luis Curras met with Respondent Huntington to discuss some deficiencies that were noted during a previous inspection of the hospital pharmacy. During that meeting, Inspector Curras explained the technology described in paragraph 15 above. Respondent Huntington thereafter generated a report using the technology. Based on the report,

Respondent Huntington determined that PT Crain had been stealing controlled substances from the Pyxis CII safe.

APPLICABLE LAW

22. Every pharmacy in Nevada must be licensed by the Board to dispense dangerous drugs and/or controlled substances. NRS 639.230; NRS 639.231.

23. Additionally, every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

24. A "managing pharmacist" is a registered pharmacist who is responsible for managing the operation of the pharmacy. NRS 639.0087. This includes the duty to supervise the procurement and storage of drugs in the pharmacy. NAC 639.473(1).

25. The managing pharmacist must establish policies, procedures and systems related to the procurement and storage of drugs, the distribution of drugs to be administered to patients, and the recording of all transactions of the pharmacy required by applicable state and federal laws. NAC 639.468(4), (6) and (9).

26. A pharmacy must maintain records for controlled substances in a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy. NAC 639.485(1)(b). Additionally, a pharmacy must maintain a perpetual inventory of any controlled substance listed in schedule II. NAC 639.485(2).

27. The Board may revoke or suspend the license of any pharmacy owner, pharmacist, or pharmacy technician who has violated any Nevada law or regulation relating to the practice of pharmacy, or who has been convicted of a felony relating to the practice of pharmacy. NRS 639.210(7) & (12); NRS 639.230(5).

28. The Board may revoke or suspend the license of a managing pharmacist who has violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides. NRS 639.210(15)

29. The Board may revoke or suspend the license of a pharmacist upon finding that the pharmacist committed unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.230(5).

30. A pharmacist commits unprofessional conduct when the pharmacist performs their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

31. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d).

32. Pharmacy managers and/or pharmacists are responsible for the acts and/or omissions of the pharmacy employees under their supervision if they knew or should have known of such acts and/or omissions. NAC 639.702. Further, pharmacy owners are responsible for the acts and/or omissions of pharmacy employees regardless of whether they knew or should have known of such acts and/or omissions. NRS 639.230(5); NAC 639.945(2),

33. In addition to or in lieu of revoking or suspending a license or certificate of registration, the Board may impose an administrative fine upon the offending pharmacy or pharmacist. The fine may not exceed $10,000 for each offense. NRS 639.255(3).

COUNT ONE
Unlawful Diversion of Controlled Substances

34. Between October 28, 2019, and February 18, 2022, PT Crain knowingly or intentionally acquired or obtained possession of controlled substances by means of deception and/or subterfuge, in violation of NRS 453.331(1)(d).

35. For her criminal misconduct as alleged above, PT Crain is subject to discipline by the Board pursuant to NRS 639.210(7) and/or (12).

36. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for PT Crain's unlawful diversion of controlled substances. NRS 453.331(1)(d), NRS 639.230(5), and NAC 639.945(2).

37. Respondent Asarch is subject to discipline by the Board because Respondent Asarch knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

38. Respondent Huntington is subject to discipline by the Board because Respondent Huntington knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

COUNT TWO
Failure by Managing Pharmacist to Comply with NAC 639.485

39. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Asarch familiarized himself with the technology described in paragraph 15 above, Respondent Asarch could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

40. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Huntington familiarized himself with the technology described in paragraph 15 above, Respondent Huntington could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

41. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(15).

42. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(15).

43. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the noncompliance with NAC 639.485(2) as alleged above. NRS 639.230(5); NAC 639.945(2).

COUNT THREE
Unprofessional Conduct by a Pharmacist

44. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 11 months.

45. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of dangerous drugs and controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 6 months.

46. As the managing pharmacist for Respondent DVH, Respondent Asarch had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Asarch breached this duty.

47. As the managing pharmacist for Respondent DVH, Respondent Huntington had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Huntington breached this duty.

48. As alleged above, Respondent Asarch performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(4).

49. As alleged above, Respondent Huntington performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(4).

50. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the unprofessional conduct as alleged above. NRS 639.230(5); NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to the pharmacy license of Respondent DVH and the certificates of registration of PT Crain, Respondent Asarch, and Respondent Huntington.

DATED this 4th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **Respondent.**	**CASE NO. 22-053-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **Respondent.**	**CASE NO. 22-053-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

ELLIOTT ASARCH, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of January, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

DVH Hospital Alliance, LLC
360 S. Lola Ln.
Pahrump, NV 89048

Elliott Asarch, RPH
[redacted]Reyes Ave.
Las Vegas, NV 89141

Matthew Huntington, RPH
[redacted]Orduno St.
Las Vegas, NV 89161

Marissa Crain, PT
[redacted]Red Rock Dr
Pahrump, NV 89048

Thomas Gibson, Esq.
1601 E. Basin Ave., Ste #302
Pahrump, NV 89060

SHIRLEY HUNTING

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Elliott Asarch, RPH
Sunrise Hospital & Medical Center
Pharmacy Department
3186 S. Maryland Pkwy
Las Vegas NV 89109

Elliott Asarch, RPH
Cure 4 The Kids Foundation Patient Pharmacy
1 Breakthrough Way FL 3
Las Vegas NV 89135

SHIRLEY HUNTING

FILED
FEB 06 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC** **License No. IB02134, and** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265, and** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203, and** **MARISSA CRAIN, PT,** **Certificate of Registration No PT14524,** **Respondents.**	**Case Nos. 22-053-PH-S** **22-053-RPH-A-S** **22-053-RPH-B-S** **22-053-PT-S** **ANSWER AND NOTICE OF DEFENSE OF ELLIOTT ASARCH, RPH**

Respondent Elliott Asarch, RPH, hereby files with the Nevada State Board of Pharmacy ("Board"), his Answer and Notice of Defense to the Notice of Intended Action and Accusation ("Accusation") filed on January 9, 2024, which was received by Mr. Asarch on January 13, 2024.

ANSWER TO ACCUSATION

Jurisdiction

Mr. Asarch agrees that the Board has jurisdiction in this matter as set forth in Paragraphs 2 and 5 of the Accusation. Paragraphs 1, 3, and 4 pertain solely to Respondents DVH Hospital Alliance, LLC ("DVH"), Mr. Huntington and Ms. Crain. Mr. Asarch further answers the Factual Allegations set forth in the Accusation as follows:

Factual Allegations: Paragraphs 6-21

Paragraph 6: Paragraph 6 pertains only to DVH and does not require a response from Mr. Asarch.

Paragraph 7: Mr. Asarch is without sufficient personal knowledge to fully respond to paragraph 7 but acknowledges that Ms. Crain was employed at DVH during the time that he worked at the facility, with the exception of a multi-month medical leave of absence taken by Ms. Crain in 2021.

Paragraph 8: Mr. Asarch is without sufficient personal knowledge to respond to the factual assertions set forth in Paragraph 8, but based on information Mr. Asarch has reviewed related to this matter, he believes these factual assertions to be correct to the extent that Ms. Crain stole controlled substances from DVH.

Paragraph 9: Mr. Asarch is without sufficient personal knowledge to respond to the factual assertions set forth in Paragraph 9.

Paragraph 10: Mr. Asarch believes that he was employed by DVH approximately between September 13, 2020, rather than November 13, 2020, and October 5, 2021, but is without sufficient personal knowledge to respond to the remaining factual allegations set forth in Paragraph 10.

Paragraph 11: Paragraph 11 pertains solely to Mr. Huntington and Ms. Crain and does not require a response from Mr. Asarch.

Paragraph 12: Mr. Asarch believes to the best of his knowledge and recollection that the factual allegations set forth in Paragraph 12 are accurate.

Paragraph 13: Mr. Asarch believes to the best of his knowledge and recollection that the factual allegations set forth in Paragraph 13 are accurate.

Paragraph 14: Mr. Asarch believes to the best of his knowledge and recollection that the factual allegations set forth in Paragraph 14 are accurate.

Paragraph 15: Mr. Asarch is in agreement with the factual allegations set forth in Paragraph 15 to the extent that the Pyxis system did allow the tracking of dangerous drugs and controlled substances but is without sufficient recollection to respond to the capabilities of the Pyxis system in place at DVH during the time he worked at the facility.

Paragraph 16: Mr. Asarch agrees with the factual allegations contained in Paragraph 16 to the extent that Ms. Crain's duties did include restocking the Pyxis MedStations.

Paragraph 17: Mr. Asarch agrees with the factual allegations contained in Paragraph 17 to the extent that Ms. Crain often worked without supervision when restocking Pyxis Medstations, which is a standard institutional pharmacy practice. Ms. Crain worked under pharmacist supervision for all duties performed in the central pharmacy, including but not limited to controlled substances transactions involving the CII safe. Due to the limited number of pharmacy staff on duty during the week and which was further limited during the weekends, it was difficult to find a witness for transporting drugs between the CII safe and the Pyxis MedStations. However, Mr. Asarch asserts that inventories did require a witness and the Pyxis system should not have allowed Ms. Crain to inventory without a witness after Mr. Asarch modified access to the Pyxis system as described in Paragraph 19.

Paragraph 18: Mr. Asarch is without sufficient personal knowledge to respond to the factual allegations contained in Paragraph 18.

Paragraph 19: Mr. Asarch agrees with the factual allegations set forth in Paragraph 19 only to the extent that he believes he was unaware of all reports that were available through the Pyxis system at the time in question. However, Mr. Asarch asserts that daily automated reports

were being run through the Pyxis system which were reviewed by the staff pharmacist or himself. Further, Mr. Asarch asserts that when he became managing pharmacist at DVH, he identified that Ms. Crain had inappropriate access to the Pyxis records and corrected the issue. However, Mr. Asarch believes that these corrected settings must have been changed at some point by other unidentified individuals. The Pyxis system in use by DVH at the time did not allow for remote modification of settings, or remote running of reports. If modifications were to be made to the system, an individual would have needed to be physically at a Pyxis station.

Paragraph 20: The factual allegations contained in Paragraph 20 pertain solely to Mr. Huntington and do not require a response from Mr. Asarch.

Paragraph 21: The factual allegations contained in Paragraph 21 pertain solely to Mr. Huntington and do not require a response from Mr. Asarch.

Applicable Law: Paragraphs 22-33

Paragraph 22: Mr. Asarch agrees that Paragraph 22 accurately reflects the provisions of NRS 639.230 and 639.231.

Paragraph 23: Mr. Asarch agrees that Paragraph 23 accurately reflects provisions of NRS 639.220(1).

Paragraph 24: Mr. Asarch agrees that Paragraph 24 accurately reflects the provisions of NRS 639.0087 and NAC 639.473(1).

Paragraph 25: Mr. Asarch agrees that Paragraph 25 accurately reflects provisions of NAC 639.468 (4), (6), and (9).

Paragraph 26: Mr. Asarch agrees that Paragraph 26 accurately reflects the provisions of NAC 639.485(1)(b) and (2).

Paragraph 27: Mr. Asarch agrees that Paragraph 27 accurately reflects the provisions of NRS 639.210(7) and (12), however agrees that the Paragraph accurately reflects the provisions of NRS 639.230(5) only to the extent that a violation of the provisions of Chapter 639 by pharmacy personnel under the supervision of a managing pharmacist is ground for disciplinary action against the pharmacy.

Paragraph 28: Mr. Asarch agrees that Paragraph 28 accurately reflects the provisions of NRS 639.210(15).

Paragraph 29: Mr. Asarch agrees that Paragraph 29 accurately reflects the provisions of NRS 639.210(4) to the extent that the Board may take disciplinary action against any holder of a license or certificate issued by the Board. Mr. Asarch contends that Paragraph 29 does not accurately reflect the contents of NRS 639.230(5).

Paragraph 30: Mr. Asarch agrees that Paragraph 30 accurately reflects the provisions of NAC 639.945(1)(i).

Paragraph 31: Mr. Asarch agrees that Paragraph 31 accurately reflects the provisions of NRS 453.331(1)(d) as it relates to criminal activity.

Paragraph 32: Mr. Asarch agrees that Paragraph 32 accurately reflects the provisions of NAC 639.702 and NRS 639.230(5), however Paragraph 32 does not accurately reflect the provisions of NAC 639.945(2).

Paragraph 33: Mr. Asarch agrees that Paragraph 33 accurately reflects the provisions of NRS 693.255(3).

Counts: Paragraphs 34-50

Count One (Paragraphs 34-38):

Mr. Asarch denies the allegations set forth in Count I as they relate to him in Paragraph 37.

Count Two (Paragraphs 39-43): Mr. Asarch denies the allegations contained in Count Two as they pertain to him in Paragraphs 39 and 41.

Count Three (Paragraphs 44-50): Mr. Asarch denies the allegations set forth in Count III as they pertain to him in Paragraphs 44, 46 and 48.

NOTICE OF DEFENSE/MITIGATING INFORMATION

Mr. Asarch worked as managing pharmacist at DVH in Pahrump for approximately thirteen months between September 2020 and October 2021 after transferring from another facility within the same healthcare system. During the time that Mr. Asarch acted as managing pharmacist, he typically worked Monday through Friday, 8:00 a.m. through 5:00 p.m. During the week the pharmacy would be staffed by the managing pharmacist, one staff pharmacist and a pharmacy technician. On the weekend, the pharmacy would be staffed by a staff pharmacist and pharmacy technician.

Drugs ordered by the DVH pharmacy would be received and the order audited. The drugs received in the order would them be placed in the CII Pyxis safe in the presence of two licensed individuals. Transfer of drugs from the CII Pyxis safe to the Pyxis MedStations was usually performed by a pharmacy technician. From the Pyxis MedStation, the drug would be dispensed to patients per provider orders. Inventories of the Pyxis system were regularly performed.

Upon starting his position at DVH, Mr. Asarch discovered that Ms. Crain had inappropriate access to the Pyxis system which allowed her to perform inventories without a witness. Once Mr.

Asarch identified this issue, he modified her access so that she was unable to perform inventories without a witness. As discussed above, Mr. Asarch believes the Ms. Crain's Pyxis access was at some point modified by someone. Modifications to Pyxis access system in place at DVH at the time of the incidents in question could only be done while physically at a Pyxis station; Mr. Asarch is unaware of who may have modified Ms. Crain's access.

Mr. Asarch did have the Pyxis system running an automated report once daily. Mr. Asarch relied heavily on the staff pharmacist to review the daily report as Mr. Asarch was required to be out of the pharmacy often during the thirteen months due to duties related to the roll out of COVID vaccinations including but not limited to planning of vaccination clinics, conducting on-site hospital vaccination clinics, and preparing and administering vaccines off-site for Nye County. While Mr. Asarch was running a daily report, he does acknowledge that a different report may have been more useful in identifying Ms. Crain's diversion, which he is now aware was occurring before he acted as managing pharmacist at DVH and continued after he left the position. While daily reports were being run, the timing of the reports was important as well as ideally no drugs should be in movement at the time the report was run. While an automated report was programed to run daily, there is no way to be certain that the report generated by the Pyxis would have always been accurate due to drug movement.

Mr. Asarch asserts that he did put in place safeguards against diversion, however due to DVH being a small but busy rural hospital, he did not have at his disposal all the tools that he would in a larger facility. With the limitations of a rural hospital and Mr. Asarch's COVID related duties, Ms. Crain was unfortunately able to manipulate the system to divert controlled substances.

However, Mr. Asarch denies that he has in any manner violated any provision of NRS/NAC Chapters 639 as alleged in the Accusation in this matter.

Respectfully submitted this 6th of February, 2024.

Lyn E. Beggs, Esq.
Attorney for Respondent Elliott Asarch, RPh

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **Respondent.**	**Case Nos. 22-053-RPH-A-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Elliott Asarch ("Respondent"), by and through counsel, Lyn Beggs, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that after having consulted with counsel, he understands the terms of this Stipulation and has executed it knowingly and voluntarily.

4. Respondent acknowledges that he is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with its provisions, Respondent

hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged against Respondent in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, Respondent agrees to the following:

A. As of the effective date of this Order, Respondent's Certificate of Registration No. 19265 shall be **SUSPENDED** for a period of one (1) year; however, the execution of the suspension shall be stayed, and Respondent shall be authorized to engage in the practice of pharmacy in Nevada provided that Respondent satisfies the terms and conditions stated below.

B. Respondent shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs.

C. On or before May 1, 2024, Respondent shall pay an administrative fine in the amount of Two Thousand Five Hundred and 00/100 Dollars ($2,500.00), payable by *certified check, cashier's check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

D. On or before May 1, 2024, Respondent shall partially reimburse the Board in the amount of Five Hundred and 00/100 Dollars ($500.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check, cashier's check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521

8. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent or his attorney fails to appear for the meeting.

9. Respondent understands and acknowledges that the Board is not obligated to accept this Stipulation. Assuming the Board accepts this Stipulation, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r-2 and 45 CFR Part 60.

10. If the Board accepts this Stipulation, failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may, pursuant to NRS 622A.410(1), impose additional discipline not inconsistent with the provisions of NRS chapter 639.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation.

AGREED:

Signed this 13th day of February 2024.

ELLIOTT ASARCH, RPH
Certificate of Registration No. 19265

Signed this 13th day of February 2024.

NEVADA STATE BOARD OF PHARMACY

By

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

Lyn Beggs, Esq.
Nevada Bar No. 6248
Attorney for Respondent Elliott Asarch

DECISION AND ORDER

As to Respondent Elliott Asarch, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 23-053-RPH-A-S, and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of March 2024.

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DVH HOSPITAL ALLIANCE, LLC,** **Pharmacy License No. IB02134,** **ELLIOTT ASARCH, RPH,** **Certificate of Registration No. 19265,** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **and,** **MARISSA CRAIN, PT,** **Certificate of Registration No. PT14524,** **Respondents.**	**CASE NOS. 22-053-PH-S** **22-053-RPH-A-S** **22-053-RPH-B-S** **22-053-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent DVH Hospital Alliance, LLC ("Respondent DVH"), because Respondent DVH is licensed by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent DVH holds pharmacy license number PH02587.

2. The Board has personal jurisdiction over Respondent Elliott Asarch ("Respondent Asarch") because Respondent Asarch is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Asarch holds certificate of registration no. 19265.

3. The Board has personal jurisdiction over Respondent Matthew Huntington ("Respondent Huntington") because Respondent Huntington is a registered pharmacist authorized by the Board to dispense dangerous drugs and controlled substances in Nevada. Respondent Huntington holds certificate of registration no. 18203.

4. The Board has personal jurisdiction over Respondent Marissa Crain ("PT Crain") because PT Crain was formerly registered by the Board to work as a pharmacy technician. The allegations below relate to PT Crain's employment as a pharmacy technician between December 2019 and February 2022. PT Crain held certificate of registration no. PT14524, which expired on October 31, 2022.

5. The Board has jurisdiction over the subject matter of this accusation because it alleges violations pertaining to the possession, control, and distribution of dangerous drugs and controlled substances.

FACTUAL ALLEGATIONS

6. At all times relevant to this accusation, Respondent DVH operated a pharmacy within the Desert View Hospital ("DVH Hospital"), located at 360 South Lola Lane in Pahrump, Nevada.

7. Between October 28, 2019, and February 18, 2022, Respondent DVH employed PT Crain as a pharmacy technician.

8. During her employment with Respondent DVH, PT Crain stole a large quantity of controlled substances. The stolen items included at least 3,243 tablets of hydrocodone, oxycodone, and alprazolam, 103 vials of fentanyl, 218 vials of morphine, and 50 vials of lorazepam, meperidine, and midazolam.

9. In February 2022, PT Crain admitted to stealing controlled substances from DVH Hospital. Respondent DVH thereafter terminated PT Crain's employment at DVH Hospital. In September 2022, PT Crain pleaded guilty to felony charges of unlawful possession of a controlled substance and embezzlement.

10. Between November 13, 2020, and October 5, 2021, Respondent DVH employed Respondent Asarch as its managing pharmacist. During this time frame, while under Respondent Asarch's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

11. Between October 6, 2021, and February 18, 2022, Respondent DVH employed Respondent Huntington as its managing pharmacist. During this time frame, while under Respondent Huntington's direct or indirect supervision, PT Crain stole a large percentage of the controlled substances described in paragraph 8 above.

12. At all times relevant to this accusation, Respondent DVH owned or leased a Pyxis automated medication dispensing system. Respondent DVH used the Pyxis system to store and dispense dangerous drugs and controlled substances.

13. The Pyxis system consisted of a Pyxis CII safe, which was located in the pharmacy of the DVH Hospital. The Pyxis system also consisted of Pyxis MedStations, which were located at different places outside the pharmacy but inside the DVH Hospital where designated medical practitioners had access to them.

14. The Pyxis CII safe served as the central vault for storing dangerous drugs and controlled substances in the hospital pharmacy. The Pyxis MedStations served as automated dispensing devices from which medical practitioners removed dangerous drugs and controlled substances for administering to patients of the DVH Hospital.

15. The Pyxis system is equipped with digital technology that tracks dangerous drugs and controlled substances when they are removed from the Pyxis CII safe and then transferred to the Pyxis MedStations. The system also tracks removals from and/or deposits to the Pyxis MedStations. The Pyxis system is capable of generating a report that identifies in real time all such transactions involving dangerous drugs and controlled substances. If used properly, the Pyxis system provides the means by which a hospital pharmacy can maintain a perpetual inventory of controlled substances.

16. During her employment at DVH Hospital, PT Crain was responsible for restocking the Pyxis MedStations. This required her to remove dangerous drugs and controlled substances from the Pyxis CII safe and then transport them to the Pyxis MedStations.

17. While performing her restocking duties, PT Crain frequently worked without supervision. PT Crain was rarely if ever accompanied by another hospital employee when she removed inventory from the Pyxis CII safe and/or transported it to the Pyxis MedStations.

18. While performing her restocking duties, PT Crain often pretended to restock the Pyxis MedStations with inventory removed from the Pyxis CII safe. In fact, PT Crain stole much of the inventory that she removed from the Pyxis CII safe, never transferring it to the Pyxis MedStations and/or never returning it to the Pyxis CII safe.

19. During his tenure as managing pharmacist at DVH Hospital, Respondent Asarch neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

20. During his tenure as managing pharmacist at DVH Hospital, Respondent Huntington neglected to familiarize himself with the Pyxis technology described in paragraph 15 above. As a result, Respondent DVH did not maintain an automated inventory system for tracking dangerous drugs and controlled substances. Instead, Respondent DVH manually tracked its inventory of dangerous drugs and controlled substances. Working without supervision, PT Crain easily falsified these records of inventory.

21. In February 2022, Board Inspector Luis Curras met with Respondent Huntington to discuss some deficiencies that were noted during a previous inspection of the hospital pharmacy. During that meeting, Inspector Curras explained the technology described in paragraph 15 above. Respondent Huntington thereafter generated a report using the technology. Based on the report,

Respondent Huntington determined that PT Crain had been stealing controlled substances from the Pyxis CII safe.

APPLICABLE LAW

22. Every pharmacy in Nevada must be licensed by the Board to dispense dangerous drugs and/or controlled substances. NRS 639.230; NRS 639.231.

23. Additionally, every pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

24. A "managing pharmacist" is a registered pharmacist who is responsible for managing the operation of the pharmacy. NRS 639.0087. This includes the duty to supervise the procurement and storage of drugs in the pharmacy. NAC 639.473(1).

25. The managing pharmacist must establish policies, procedures and systems related to the procurement and storage of drugs, the distribution of drugs to be administered to patients, and the recording of all transactions of the pharmacy required by applicable state and federal laws. NAC 639.468(4), (6) and (9).

26. A pharmacy must maintain records for controlled substances in a manner that establishes the receipt, distribution and destruction of all controlled substances handled by the pharmacy. NAC 639.485(1)(b). Additionally, a pharmacy must maintain a perpetual inventory of any controlled substance listed in schedule II. NAC 639.485(2).

27. The Board may revoke or suspend the license of any pharmacy owner, pharmacist, or pharmacy technician who has violated any Nevada law or regulation relating to the practice of pharmacy, or who has been convicted of a felony relating to the practice of pharmacy. NRS 639.210(7) & (12); NRS 639.230(5).

28. The Board may revoke or suspend the license of a managing pharmacist who has violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides. NRS 639.210(15)

29. The Board may revoke or suspend the license of a pharmacist upon finding that the pharmacist committed unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.230(5).

30. A pharmacist commits unprofessional conduct when the pharmacist performs their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

31. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d).

32. Pharmacy managers and/or pharmacists are responsible for the acts and/or omissions of the pharmacy employees under their supervision if they knew or should have known of such acts and/or omissions. NAC 639.702. Further, pharmacy owners are responsible for the acts and/or omissions of pharmacy employees regardless of whether they knew or should have known of such acts and/or omissions. NRS 639.230(5); NAC 639.945(2),

33. In addition to or in lieu of revoking or suspending a license or certificate of registration, the Board may impose an administrative fine upon the offending pharmacy or pharmacist. The fine may not exceed $10,000 for each offense. NRS 639.255(3).

COUNT ONE
Unlawful Diversion of Controlled Substances

34. Between October 28, 2019, and February 18, 2022, PT Crain knowingly or intentionally acquired or obtained possession of controlled substances by means of deception and/or subterfuge, in violation of NRS 453.331(1)(d).

35. For her criminal misconduct as alleged above, PT Crain is subject to discipline by the Board pursuant to NRS 639.210(7) and/or (12).

36. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for PT Crain's unlawful diversion of controlled substances. NRS 453.331(1)(d), NRS 639.230(5), and NAC 639.945(2).

37. Respondent Asarch is subject to discipline by the Board because Respondent Asarch knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

38. Respondent Huntington is subject to discipline by the Board because Respondent Huntington knew or should have known that PT Crain unlawfully diverted controlled substances in violation of NRS 453.331(1)(d). NAC 639.702.

COUNT TWO
Failure by Managing Pharmacist to Comply with NAC 639.485

39. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Asarch familiarized himself with the technology described in paragraph 15 above, Respondent Asarch could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

40. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to maintain a perpetual inventory of Schedule II controlled substances as required by NAC 639.485(2). Had Respondent Huntington familiarized himself with the technology described in paragraph 15 above, Respondent Huntington could easily have maintained a perpetual inventory of all controlled substances in the possession of Respondent DVH.

41. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(15).

42. For his failure to comply with NAC 639.485(2) as alleged above, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(15).

43. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the noncompliance with NAC 639.485(2) as alleged above. NRS 639.230(5); NAC 639.945(2).

COUNT THREE
Unprofessional Conduct by a Pharmacist

44. Between November 13, 2020, and October 5, 2021, while serving as the managing pharmacist for Respondent DVH, Respondent Asarch failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 11 months.

45. Between October 6, 2021, and February 18, 2022, while serving as the managing pharmacist for Respondent DVH, Respondent Huntington failed to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of dangerous drugs and controlled substances within the DVH Hospital. As a result, PT Crain, without detection, unlawfully diverted a large quantity of controlled substances over a period of more than 6 months.

46. As the managing pharmacist for Respondent DVH, Respondent Asarch had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Asarch breached this duty.

47. As the managing pharmacist for Respondent DVH, Respondent Huntington had a legal duty to implement and/or maintain a reliable system and/or policies and procedures for tracking the possession, control, and distribution of controlled substances within the DVH Hospital. *See* NRS 639.220(1); NRS 639.0087; NAC 639.473(1); NAC 639.468(4), (6) and (9); NAC 639.485(1)(b) and (2). Through his negligence, inattention, and/or incompetence, Respondent Huntington breached this duty.

48. As alleged above, Respondent Asarch performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Asarch is subject to discipline by the Board pursuant to NRS 639.210(4).

49. As alleged above, Respondent Huntington performed his duties as the holder of a license or registration issued by the Board in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i). Therefore, Respondent Huntington is subject to discipline by the Board pursuant to NRS 639.210(4).

50. Respondent DVH is subject to discipline by the Board because Respondent DVH is responsible as the pharmacy owner for the unprofessional conduct as alleged above. NRS 639.230(5); NAC 639.945(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to the pharmacy license of Respondent DVH and the certificates of registration of PT Crain, Respondent Asarch, and Respondent Huntington.

DATED this 9th day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **Respondent.**	**CASE NO. 22-053-RPH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW HUNTINGTON, RPH,** **Certificate of Registration No. 18203,** **Respondent.**	**CASE NO. 22-053-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MATTHEW HUNTINGTON, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 10th day of January, 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

DVH Hospital Alliance, LLC
360 S. Lola Ln.
Pahrump, NV 89048

Elliott Asarch, RPH
[redacted] Reyes Ave.
Las Vegas, NV 89141

Matthew Huntington, RPH
[redacted] Orduno St.
Las Vegas, NV 89161

Marissa Crain, PT
[redacted] Red Rock Dr
Pahrump, NV 89048

Thomas Gibson, Esq.
1601 E. Basin Ave., Ste #302
Pahrump, NV 89060

SHIRLEY HUNTING

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. DVH HOSPITAL ALLIANCE, LLC, License No. IB02134, and MATTHEW HUNTINGTON, RPH, Certificate of Registration No. 18203, Respondents.	Case Nos. 22-053-PH-S 22-053-RPH-B-S STIPULATION AND ORDER

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondents DVH Hospital Alliance, LLC, and Matthew Huntington (together "Respondents"), by and through counsel, Maria Nutile, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondents and this matter.

2. The Board's staff properly served Respondents with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondents acknowledge that after having consulted with counsel, they understand the terms of this Stipulation, and that they have executed it knowingly and voluntarily.

4. Respondents acknowledge that they are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondents under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondents have failed to comply with its provisions,

Respondents hereby freely and voluntarily waive the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Respondents admit that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged against each of them in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent DVH Hospital Alliance, LLC ("Respondent DVH") agree to the following:

A. In lieu of risking a possible suspension or revocation of its pharmacy license by proceeding with a hearing on the merits, Respondent DVH agrees to submit to four quarterly inspections of its pharmacy within the Desert View Hospital, located at 360 South Lola Lane in Pahrump, Nevada. These inspections will be conducted by the Board's inspectors for the calendar quarters ending June 30, 2024, September 30, 2024, December 31, 2024, and March 31, 2025, or at such other quarterly intervals as the parties may agree.

B. Respondent DVH further agrees that its registered pharmacists will maintain a perpetual inventory of all controlled substances in stock in the pharmacy; that they will supply the Board's inspectors with copies of the pharmacy's most current policies and procedures to reflect the maintenance of a perpetual inventory for all controlled substances; that they will supply the Board's inspectors with copies of the pharmacy's most current policies and procedures concerning the investigation and reporting of suspected controlled substance losses; and that they will make reasonable updates to policies and procedures as the Board's inspectors may recommend.

C. On or before May 1, 2024, Respondent DVH shall pay an administrative fine in the amount of Ten Thousand and 00/100 Dollars ($10,000.00), payable by *certified check, cashier's check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

D. On or before May 1, 2024, Respondent DVH shall partially reimburse the Board in the amount of One Thousand and 00/100 Dollars ($1,000.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check, cashier's check,* or *money order* written to the "**Nevada State Board of Pharmacy.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent Matthew Huntington ("Respondent Huntington") agree to the following:

A. As of the effective date of this Order, Respondent Huntington's Certificate of Registration No. 18203 shall be **SUSPENDED** for a period of one (1) year; however, the execution of the suspension shall be stayed, and Respondent Huntington shall be authorized to engage in the practice of pharmacy in Nevada provided that Respondent Huntington satisfies the terms and conditions stated below.

B. Respondent Huntington shall not violate any federal or state law pertaining to the dispensing of controlled substances and/or dangerous drugs.

C. Respondent Huntington shall, as long as he remains employed by Respondent DVH as the managing pharmacist at the Desert View Hospital, facilitate the performance by Respondent DVH of its responsibilities as described above.

D. On or before May 1, 2024, Respondent Huntington shall pay an administrative fine in the amount of Two Thousand Five Hundred and 00/100 Dollars ($2,500.00), payable by *certified check, cashier's check,* or *money order* written to the "**State of Nevada, Office of the Treasurer.**" Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521.

E. On or before May 1, 2024, Respondent Huntington shall partially reimburse the Board in the amount of Five Hundred and 00/100 Dollars ($500.00) for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *certified check,*

cashier's check, or *money order* written to the "**Nevada State Board of Pharmacy**." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondents or their attorney fail to appear for the meeting.

10. Respondents understand and acknowledge that the Board is not obligated to accept this Stipulation. Assuming the Board accepts this Stipulation, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board accepts this Stipulation, failure by Respondents to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondents, or either of them as applicable, to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may, pursuant to NRS 622A.410(1), impose additional discipline not inconsistent with the provisions of NRS chapter 639.

12. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

13. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation.

[Remainder of this Page Left Blank]

AGREED:

Signed this 9th day of February 2024.

MATTHEW HUNTINGTON, RPH
Certificate of Registration No. 18203

DVH HOSPITAL ALLIANCE, LLC
Pharmacy License No. IB02134

By _____
Print Susan K. Davila
Title CEO

Signed this 9th day of February 2024.

NEVADA STATE BOARD OF PHARMACY

By _____
GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

_____
Maria Nutile, Esq.
Nevada Bar No. 7847
Attorney for Respondents

DECISION AND ORDER

As to Respondent DVH Hospital Alliance, LLC, and Respondent Matthew Huntington, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 23-053-PH-S and Case No. 25-053-RPH-B-S, respectively, and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of March 2024.

_____
Helen Park, President
Nevada State Board of Pharmacy

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FILED
AUG 31 2023
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHERYL SAUNDERS, APRN,** **Certificate of Registration No. CS27884,** **Respondent.**	**CASE NO. 23-167-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Cheryl Saunders, APRN ("Saunders"), because Saunders holds a certificate of registration issued by the Board that authorizes her to prescribe dangerous drugs and controlled substances in Nevada. Thompson holds certificate of registration no. CS27884, which was issued by the Board pursuant to NRS 639.2351, NRS 453.226, and NRS 453.231.

2. The Board has jurisdiction over the subject matter of this accusation because, at the time of the violations alleged herein, Saunders was engaged in the "practice of pharmacy" as that term is defined at NRS 639.0124.

FACTUAL ALLEGATIONS

3. Saunders is an advanced practice registered nurse licensed by the Nevada State Board of Nursing to practice advanced nursing in Nevada. Between November 1, 2021, and May 22, 2023, Saunders practiced advanced nursing at the Aesthetics MedSpa, located at 6295 Sharlands Avenue, Suite C1, in Reno, Nevada.

4. At all times relevant to this accusation, Jasmine Wells (Wells) owned and/or operated the Aesthetics MedSpa.

5. Wells is not and has never been a "practitioner" as that term is defined at NRS 639.012 and NRS 454.00958.

6. The Aesthetics MedSpa is not and has never been a "medical facility" as that term is defined in NRS 449.0151.

7. The Aesthetics MedSpa is not and has never been "the office of a physician or physician assistant" within the meaning of NRS 454.217(1)(c).

8. At all times relevant to this accusation, Saunders was a "practitioner" as that term is defined at NRS 639.0125 and NRS 454.00958.

9. In 2021 and 2022, Saunders worked on site at the Aesthetics MedSpa, where she injected customers with botulinum toxin type A and various dermal fillers.

10. Beginning in July of 2022, Saunders worked with and/or occasionally supervised Kylie Shay Sondermann ("Sondermann"), a registered nurse who also injected customers with botulinum toxin type A and various dermal fillers.

11. Sondermann is not and has never been a "practitioner" as that term is defined at NRS 639.0125 and NRS 454.00958.

12. Botulinum toxin type A and injectable dermal fillers are "dangerous drugs" as that term is defined at NRS 454.201.

13. In January of 2023, Saunders moved to Virginia, where she was employed full-time as a nurse for the Deerfield Correctional Facility in Capron, Virginia. Between January of 2023 and May 22, 2023, Saunders was concurrently employed as the "medical director" of the Aesthetics MedSpa in Reno, Nevada.

14. Saunders was a "medical director" in name only and did not perform the duties that one would reasonably associate with a medical director.

15. Between January of 2023 and May 22, 2023, while working in Virginia, Saunders procured dangerous drugs for the Aesthetics MedSpa and caused them to be shipped to the Aesthetics MedSpa. Sondermann possessed, stored, and/or administered these drugs upon their delivery to the Aesthetics MedSpa.

16. Between January of 2023 and May 22, 2023, Sondermann possessed, stored, and/or administered dangerous drugs at the direction of Wells and without supervision or direction by Saunders or any other practitioner.

17. Between January of 2023 and May 22, 2023, Sondermann administered dangerous drugs at the direction of Wells and without an order issued by Saunders or any other practitioner.

18. Between July of 2022 and May 22, 2023, Saunders became aware that Sondermann had possessed, stored, and/or administered dangerous drugs in the course of their mutual employment with the Aesthetics MedSpa, often at the direction of Wells and without supervision or direction by Saunders or another practitioner.

19. Between July of 2022 and May 22, 2023, Saunders became aware that Sondermann had administered dangerous drugs in the course of their mutual employment with the Aesthetics MedSpa, often at the direction of Wells and without an order issued by Saunders or another practitioner.

20. At various times between July of 2022 and May 22, 2023, Wells falsely informed Saunders that Sondermann was working under the supervision of a practitioner other than Saunders. On information and belief, Saunders knew or should have known that Sondermann was not working under the supervision of a practitioner.

21. At no time between July of 2022 and May 22, 2023, was Sondermann licensed by the Board to possess, store, and/or administer dangerous.

22. On May 17, 2023, Board Investigator Monica S. Segedy and Board Inspector Mui C. Lee conducted an unannounced site visit to the Aesthetics MedSpa. While on the premises, they observed the locations where the Aesthetics MedSpa stored its dangerous drugs. One of these locations was a locked refrigerator and the other locations were locked cabinets. Upon obtaining the codes and

opening the locks, Investigator Segedy and Inspector Lee observed that the Aesthetics MedSpa had commingled expired and unexpired injectable drugs.

23. While on the premises of the Aesthetics MedSpa, Investigator Segedy reviewed business and employment records and appointment logs. These records showed that Sondermann had possessed, stored, and/or administered dangerous drugs at various times when there was no practitioner on the premises of the Aesthetics MedSpa.

24. On May 17, 2023, Investigator Segedy interviewed Wells. Wells stated that Saunders had been consulting with patients via "telemedicine" because of her residence in Virginia. In a separate interview with Investigator Segedy, Saunders stated that she had never practiced telemedicine while employed by the Aesthetics MedSpa.

25. On July 3, 2023, Investigator Segedy conducted a second interview with Wells after learning that Saunders and another practitioner had terminated their employment with the Aesthetics MedSpa. When Segedy asked whether Wells had hired a new practitioner, Wells responded that she had hired Rose Parizo, an advanced practice registered nurse. Parizo later denied that she had accepted an offer of employment from Wells.

26. On July 19, 2023, the Board issued a cease-and-desist letter to Wells, ordering her to cease and desist from operating the business of the Aesthetics MedSpa until such time as she employs a practitioner with the authority to possess, store, and administer dangerous drugs and to properly supervise the activities of Sondermann.

27. On August 1, 2023, the Board issued a cease-and-desist letter to Sondermann, ordering her to cease and desist from possessing, storing, and/or administering dangerous drugs while not under the supervision or direction of a practitioner.

APPLICABLE LAW

28. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions

of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. *See* NRS 639.210(12).

29. Additionally, the Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

30. A practitioner's conduct is deemed unprofessional and contrary to the public interest if the person performs his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful, or negligent manner, or if the person aids or abets a person not licensed to practice pharmacy in Nevada. NAC 639.945(1)(i) and (j).

31. "'Practice of pharmacy' includes, but is not limited to, the . . . [p]erformance or supervision of activities associated with manufacturing, compounding, labeling, dispensing and distributing of a drug, including the receipt, handling and storage of prescriptions and other confidential information relating to patients." NRS 639.0124(1)(a).

32. In lieu of revoking or suspending a practitioner's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

33. It is unlawful to possess, store, or administer dangerous drugs, including botulinum toxin type A and injectable dermal fillers, except as authorized by NRS 454.213. "Administer" means the direct application of a [dangerous drug] . . . whether by injection, inhalation, ingestion or any other means, to the body of a patient or research subject." NRS 454.191.

34. Pursuant to NRS 454.213, a registered nurse may not possess, store, or administer dangerous drugs except at the direction of a supervising practitioner.

35. It is unlawful for a registered nurse to inject botulinum toxin type A in a patient or customer "at a location other than a medical facility, as defined in NRS 449.0151, or the office of a physician or physician assistant licensed [pursuant to applicable statutes]." NRS 454.217.

36. A practitioner who maintains a stock of controlled substances and/or dangerous drugs must not commingle expired substances and unexpired substances in a storage area from which the substances are withdrawn from inventory for administering or dispensing to patients. NAC 639.050(2); NAC 639.473.

37. A practitioner is subject to discipline if the practitioner causes or allows a dangerous drug to be dispensed in a manner not authorized by NRS 454.215 and NRS 454.301. *See* NRS 639.100; NRS 639.210(12). The term "dispense" includes the prescribing by a practitioner, administering, packaging, labeling, or compounding necessary to prepare a substance for delivery to a patient. NRS 639.0065; NRS 453.056.

COUNT ONE

Assisting or Abetting in Violations of NRS 454.215 and/or NRS 454.301

38. Between January of 2023 and May 22, 2023, while working in Virginia, Saunders procured dangerous drugs for the Aesthetics MedSpa and caused them to be shipped to the Aesthetics MedSpa.

39. Upon their delivery to the Aesthetics MedSpa, Sondermann possessed, stored, and/or administered the dangerous drugs procured by Saunders as alleged above.

40. Saunders knew or should have known that Sondermann possessed, stored, and/or administered these dangerous drugs without any supervision or direction by a practitioner.

41. Sondermann was not licensed by the Board to possess, store, and/or administer dangerous drugs in the manner alleged above.

42. Saunders knew or should have known that Sondermann was not licensed by the Board to possess, store, and/or administer dangerous drugs.

43. By procuring dangerous drugs with actual or constructive knowledge of Sondermann's unlicensed activity as alleged above, Saunders assisted or abetted Sondermann in violating NRS 454.215 and NRS 454.310.

44. Saunders' conduct as alleged above amounts to a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT TWO
Assisting or Abetting the Unlicensed Practice of Pharmacy

45. Between January of 2023 and May 22, 2023, while working in Virginia, Saunders procured dangerous drugs for the Aesthetics MedSpa and caused them to be shipped to the Aesthetics MedSpa.

46. Upon their delivery to the Aesthetics MedSpa, Sondermann possessed, stored, and/or administered the dangerous drugs procured by Saunders as alleged above.

47. Saunders knew or should have known that Sondermann possessed, stored, and/or administered these dangerous drugs without any supervision or direction by a practitioner.

48. Sondermann was not licensed by the Board to possess, store, and/or administer dangerous drugs.

49. Saunders knew or should have known that Sondermann was not licensed by the Board to possess, store, and/or administer dangerous drugs.

50. By procuring dangerous drugs with actual or constructive knowledge of Sondermann's unlicensed activity as alleged above, Saunders assisted or abetted Sondermann in the unlicensed practice of pharmacy.

51. Saunders' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(j).

COUNT THREE
Assisting or Abetting in Violations of NAC 639.050(2) and/or NAC 639.473

52. Between January of 2023 and May 22, 2023, while working in Virginia, Saunders procured dangerous drugs for the Aesthetics MedSpa and caused them to be shipped to the Aesthetics MedSpa.

53. Upon their delivery to the Aesthetics MedSpa, Sondermann possessed, stored, and/or administered the dangerous drugs procured by Saunders as alleged above. Saunders knew or should

have known that Sondermann possessed, stored, and/or administered these dangerous drugs without any supervision or direction by a practitioner.

54. In addition to engaging in unlicensed activity, Sondermann stored the dangerous drugs procured by Saunders in locations from which Aesthetics MedSpa withdrew the drugs from inventory for administering or dispensing to patients.

55. Sondermann commingled expired drugs and unexpired drugs in the locations where Aesthetics MedSpa withdrew the drugs from inventory for administering or dispensing to patients.

56. Saunders knew or should have known that Sondermann was not trained to properly store dangerous drugs.

57. By allowing Sondermann to commingle expired and unexpired drugs as alleged above, Saunders assisted or abetted Sondermann in violations of NAC 639.050(2) and/or NAC 639.473.

58. Saunders' conduct as alleged above amounts to a violation of law for which the Board may impose administrative discipline. *See* NRS 639.210(12).

COUNT FOUR
Performing Duties in an Incompetent, Unskillful, or Negligent Manner

59. Between January of 2023 and May 22, 2023, while working in Virginia, Saunders procured dangerous drugs for the Aesthetics MedSpa and caused them to be shipped to the Aesthetics MedSpa.

60. By procuring dangerous drugs for the Aesthetics MedSpa, Saunders assumed a duty to supervise Sondermann and/or to ensure that the drugs procured by her were possessed, stored, and/or administered in accordance with all applicable statutes and regulations.

61. As alleged above, Sondermann possessed, stored, and/or administered dangerous drugs in violation of the statutes and/or regulations cited above.

62. By failing to properly supervise Sondermann, Saunders performed her duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful, or negligent manner.

63. Saunders' conduct as alleged above amounts to unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Cheryl Saunders.

DATED this 30th day of AUGUST 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHERYL SAUNDERS, APRN,** **Certificate of Registration No. CS27884,** **Respondent.**	**CASE NO. 23-167-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, April 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E. Plumb Lane
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and zunino@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of AUGUST, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHERYL SAUNDERS, APRN,** **Certificate of Registration No. CS27884,** **Respondent.**	**CASE NO. 23-167-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

CHERYL SAUNDERS, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of August 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Cheryl Saunders, APRN
[redacted] Sharlands Ave. #1
Reno, NV 89523

SHIRLEY HUNTING

FILED
SEP 22 2023
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OR PHARMACY Petitioner, v. CHERYL SAUNDERS, APRN, FNP-BC Certificate of Registration No. CS27884 Respondent.	CASE NO.: 23-167-CS-N ANSWER AND NOTICE OF DEFENSE

Ms. Cheryl Saunders, APRN, FNP-BC, ("Ms. Saunders"), by and through her counsel of record MURPHY JONES APC, in answer to the Notice of Intended Action and Accusation ("Accusation") filed in the above-entitled matter before the Nevada State Board of Pharmacy ("Board"), declares as follows:

1. Objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against her, is hereby interposed on the following grounds:

None.

2. That, in answer to the Notice of Intended Action and Accusation, Ms. Saunders admits, denies, and alleges as follows:

Ms. Saunders has recently retained legal counsel who is conducting an independent investigation into the allegations espoused in the Accusation. Ms. Saunders requests a hearing in the matter, on the merits of the case, and will provide additional information and produce relevant documentation, after her legal counsel has been afforded the opportunity to adequately prepare a defense to the Accusation. With the afore-referenced reservation, Ms. Saunders admits and denies the allegations espoused in the Notice of Intended Action and Accusation as follows:

////

I.

Ms. Saunders admits that the Board has jurisdiction over this matter.

II - III.

Ms. Saunders admits that she was employed by Aesthetics MedSpa between November 1, 2021, and May 22, 2023.

IV - XXVII.

Ms. Saunders is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph IV – XXVII and therefore denies the same.

COUNT ONE

(Assisting or Abetting in Violations of NRS 454.215 and/or NRS 454.301)

Ms. Saunders states that the allegations contained in Count One contain legal conclusions and therefore denies the same.

COUNT TWO

(Assisting or Abetting the Unlicensed Practice of Pharmacy)

Ms. Saunders states that the allegations contained in Count Two contain legal conclusions and therefore denies the same.

COUNT THREE

(Assisting or Abetting in Violations of NAC 639.050(2) and/or NAC 639.473)

Ms. Saunders states that the allegations contained in Count Three contain legal conclusions and therefore denies the same.

COUNT FOUR

(Performing Duties in an Incompetent, Unskillful, or Negligent Manner)

Ms. Saunders states that the allegations contained in Count Four contain legal conclusions and therefore denies the same.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

1. Complainant fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. Complainant's causes of action are barred by applicable statute of limitations

THIRD AFFIRMATIVE DEFENSE

3. Complainant's causes of action are barred by the doctrine of unclean hands.

FOURTH AFFIRMATIVE DEFENSE

4. Complainant's causes of action are barred by the doctrine of laches.

FIFTH AFFIRMATIVE DEFENSE

5. Complainant's causes of action are barred by the doctrines of estoppel and/or waiver.

SIXTH AFFIRMATIVE DEFENSE

6. The facts not having been fully developed, Respondent further affirmatively pleads the following affirmative defenses as may be applicable in this action: accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, status of limitations, waiver, and any other matter constituting and avoidance or affirmative defense

SEVENTH AFFIRMATIVE DEFENSE

7. Any affirmative defense(s) not explicitly made herein are hereby reserved and defense(s) asserted.

REQUEST FOR DISCOVERY

On behalf of Respondent I request the following discovery:

1. The names and addresses of any and all witnesses known by you as those intended to be called to testify at the hearing in the above-entitled proceeding;

2. Statement(s) of any and all persons named in the Accusation and/or any initial or additional pleading(s);

3. Statement(s) of any and all witnesses you propose to be called at the hearing;

4. Statement(s) of any and all person(s) having personal knowledge of the acts, omissions, and/or events which are the basis for the above-entitled proceeding;

5. Any and all writings, including but not limited to, reports of mental, physical, and blood examinations and things which you propose to offer in evidence;

6. Any and all writings and/or things which are relevant, and you believe would be admissible in evidence;

7. Any and all investigative reports made by or on behalf of the State of Nevada and/or other party pertaining to the subject matter of the above-entitle proceeding.

REQUEST FOR PRIVILEGE LOG

For any document(s) you assert is/are privileged attorney-client communication within the meaning of Nevada Revised Statute section §49.065, et seq., attorney work product, or are otherwise privileged from disclosure by law or made confidential, please produce a privilege log stating the following:

a) A description of the document to which a claim of privilege is being asserted;

b) The basis of any claim of privilege;

c) If work-product immunity is being asserted, identify the specific proceeding for which the document was prepared;

d) The date of the document;

e) The name, business address, and current job title of the originator(s) or author(s) of the document;

f) The names, business address, and current job title of the recipient of the document;

g) The job title of each recipient of the document at the time the document was prepared and at time it was received; and

h) A general description of the subject of the communication contained in the document.

DEFINITION OF TERMS

The terms "you" and "your" refer to the Board and its officials, agents, representatives, employees, investigators, attorneys, consultants, and/or any person or entity acting on behalf of.

The term "document" as used hereinabove refers to a "writing" as defined in Nevada Revised Statute section §52.225, et seq., which means handwriting, typewriting, printing, photographing, photocopying, transmitting by electronic mail or facsimile, instant messaging, digital text messaging, and every other means of recording upon any tangible thing, any form of communication or representation, including letters, words, pictures, sounds or symbols, or combinations thereof, and any record thereby created, regardless of the manner in which the record has been stored.

This request includes, but is not limited to, all stored electronically or digitally such as computers, computer hard drives, zip discs, CD-Rs, CD-RWs, DVDs, floppy diskettes, tape drives, flash memory drive, and any other digital and electronic storage media.

REQUEST TO MEET AND CONFER

Please kindly contact the undersigned to meet and confer concerning, evidentiary issues, discovery, settlement possibilities, hearing length and attorney trial availability.

DATED: September 22, 2023 By: _____

Kevin C. Murphy, Esq.
Attorney for Respondent Cheryl Saunders, APRN, FNP-BC

CERTIFICATE OF SERVICE

Case Name: **Case No.: 23-167-CS-N Cheryl Saunders, APRN, FNP-BC**

I declare:

I am employed in the law firm of MURPHY JONES APC, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter.

On **September 22, 2023**, I served the attached **ANSWER AND NOTICE OF DEFENSE** via EMAIL to the following person(s) or entity/entities:

Greg Zunino, Senior General Counsel
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy., Suite 206
Reno, NV 89521
Via Email: zunino@pharmacy.nv.gov

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed on **September 22, 2023**, at San Diego, California.

Kevin C. Murphy, Esq.
Declarant

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CHERYL SAUNDERS, APRN,** **Certificate of Registration No. CS27884,** **Respondent.**	**Case No. 23-167-CS-N** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its Senior General Counsel, Gregory L. Zunino, and Respondent Cheryl Saunders ("Respondent"), by and through her counsel, Kevin Murphy, Esq., hereby stipulate and agree as follows:

1. The Board has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent acknowledges that she understands the terms of this Stipulation, and that she has executed it knowingly and voluntarily after consulting with her attorney.

4. Respondent acknowledges that she is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration of a Board determination in a contested case, the right to appeal a Board determination in a contested case, and all other rights afforded Respondent under NRS Chapter 233B, the Nevada Administrative Procedure Act, NRS Chapter 622A, which governs administrative procedure before the Board, NRS Chapter 639, the Nevada Pharmacy Act, and NRS Chapter 453, the Nevada Uniform Controlled Substances Act.

5. Conditioned on the acceptance of this Stipulation by the Board and excluding the right to challenge any determination that Respondent has failed to comply with its provisions, Respondent

hereby freely and voluntarily waives the right to a hearing, reconsideration, appeal, and other rights related to this action as identified above.

6. Without admitting to a violation of law, Respondent admits that evidence exists, and that the Board counsel prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree as follows:

A. Respondent shall pay an administrative fine of One Thousand Five Hundred and 00/100 Dollars ($1,500.00).

B. Respondent shall partially reimburse the Board for recoverable costs of litigation and attorneys' fees in the amount of One Thousand and 00/100 Dollars ($1,000.00).

C. Upon receipt of a subpoena issued pursuant to NRS 639.246, Respondent shall appear and provide sworn testimony at an administrative hearing related to the matters alleged in the Accusation as they pertain to Aesthetics MedSpa, Jasmine Wells, and Kylie Sondermann. Respondent waives jurisdictional defenses, if any, to the Board's subpoena power.

8. Failure by Respondent to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapters 453 and 639.

9. The Board's Senior General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024, in Las Vegas, Nevada. The Board Members and Staff may discuss and deliberate regarding this Stipulation even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Upon approval of this Stipulation by the Board, Respondent shall pay the administrative fine agreed to herein by *check* or *money order* payable to "**State of Nevada, Office of the Treasurer**." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by May 1, 2024.

13. Upon approval of this Stipulation by the Board, Respondent shall pay the costs and fees agreed to herein by *check* or *money order* payable to "**Nevada State Board of Pharmacy**." Payment shall be remitted in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by May 1, 2024.

14. Subject to the approval of this Stipulation by the Board, the parties agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein.

AGREED:

Signed this ____ day of February 2024.

ID xJqbH7xxfqPzLwGs1jlyYPC

CHERYL SAUNDERS, APRN

Signed this 5th day of February 2024.

NEVADA STATE BOARD OF PHARMACY

By _____

GREGORY L. ZUNINO
Senior General Counsel
Nevada Bar No. 4805

Approved as to Form and Content:

Kevin Murphy, Esq.
Nevada Bar No. 10938
Attorney for Respondent Cheryl Saunders

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in Case No. 23-167-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this 6th day of March 2024.

Helen Park, President
Nevada State Board of Pharmacy

eSignature Details

Signer ID:	**xJqbH7xxfqPzLwGs1jfjytPC**
Signed by:	Cheryl Saunders
Sent to email:	[redacted]
IP Address:	10.0.31.254
Signed at:	Feb 7 2024, 1:22 pm PST

5P

FILED
JAN 0 2 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW M. KIKUCHI, DMD,** **Certificate of Registration Nos. CS23600,** **Respondent.**	**CASE NO. 21-087-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Matthew M. Kikuchi, D.M.D. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Since August 13, 2015, Respondent has held a license to prescribe controlled substances issued by the Board pursuant to NRS 453.226.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent has been licensed by the Board to prescribe controlled substances since August 13, 2015. NRS 453.226. Such a license authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

4. Respondent is a dentist who practices at/owns the Kikuchi Oral Surgery and Dental Implant Center. There are two main locations, with the main one being at 5765 S. Ft. Apache Rd. #110, Las Vegas, NV 89148.

5. On or about June 14, 2021, Respondent's staff called the Board and spoke with Board Inspector Jenine Davis regarding how to conduct a self-query of Respondent's prescriptions in the Prescription Monitoring Program (PMP).

6. During the conversation with Board Inspector Davis, it became clear to her that neither Respondent, nor Respondent's staff knew that Respondent had an active PMP account.

7. During the conversation, it was confirmed by Board Inspector Davis that Respondent had an active PMP account since January 19, 2016.

8. After the conversation with Respondent's staff, Board PMP Compliance Coordinator Dave Jones discovered that during the period of time from January 19, 2016, to June 13, 2021, Respondent failed to conduct a single PMP review of his prescriptions.

9. Board PMP Compliance Coordinator Jones also found that Respondent only queried two (2) individual patients in his PMP account since January 19, 2016. One patient was queried on January 19, 2016, and the other was queried on April 4, 2023. During the period January 1, 2018, to April 17, 2023, Dr. Kikuchi had over 8,000 filled Controlled Substance prescriptions for over 6,800 unique patients. Dr. Kikuchi failed to conduct a PMP review for over 6,800 patients during the review period.

APPLICABLE LAW

10. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

11. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at

least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

12. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

13. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

14. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Query PMP Every 6 Months

15. Respondent established his PMP account on January 19, 2016. Between the period of time from January 19, 2016, to June 13, 2021, Respondent never reviewed his PMP account to ensure that the information in the account concerning the practitioner, including the legitimacy or validity of the prescriptions Respondent is shown as having written was correct. Respondent was and is still required to do so every six (6) months. NRS 453.164(7).

16. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

17. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law. *See* NRS 453.164(7) and NAC 639.945(1)(i). The information regarding the

practitioner that Respondent was and still is required to look at includes information concerning the prescriptions written by the practitioner. *See* NRS 453.164(7). A check of the PMP account at least once every six (6) months ensures that a practitioner has not had their credentials stolen or duplicated and that, if they have been stolen or duplicated, the Board is notified by the practitioner of any potentially forged prescriptions in a timely manner. *See* NRS 453.164(7). The required six (6) month check of a practitioner's PMP account guards against forged controlled substance prescriptions and allows practitioners to work with the Board to stop them in real time. *See* NRS 453.164(7).

18. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

COUNT TWO

Unprofessional Conduct – Failure to Query Patients Prior to Issuing an Initial Prescription and/or for a Controlled Substance

19. Respondent established his PMP account on January 19, 2016. Between the period January 19, 2016, to April 17, 2023, Respondent only queried the PMP for two patients. The queries were conducted on January 19, 2016, and April 4, 2023.

20. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

21. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on over 6,800 patients given initial prescriptions for controlled substances in schedule I-IV, or for an opioid that is a controlled substance and listed in schedule V. *See* NRS 639.23507 and NAC 639.945(1)(i). Respondent failed to query over 6,800 patients that should have been queried as PMP records reflect that Respondent only queried two patients since Respondent's PMP account has been active. *See* NRS 639.23507.

22. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 2nd day of JANUARY 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW M. KIKUCHI, DMD,** **Certificate of Registration No. CS23600,** **Respondent.**	**CASE NO. 21-087-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW M. KIKUCHI, DMD,** **Certificate of Registration No. CS23600,** **Respondent.**	**CASE NO. 21-087-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MATTHEW M. KIKUCHI, DMD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 5th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Matthew Kikuchi, DMD
[redacted] S Ft. Apache RD [redacted]
Las Vegas, NV 89148

Matthew Kikuchi, DMD
[redacted] Hardin Dr.
Henderson, NV 89074

SHIRLEY HUNTING

FILED
JAN 25 2024
NEVADA STATE BOARD OF PHARMACY

R. CHRISTOPHER READE
Nevada Bar No. 6791
CORY READE DOWS & SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
Telephone: (702) 794-4411
Fax: (702) 794-4421
creade@crdslaw.com
Attorneys for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. MATTHEW M. KIKUCHI, DMD, Certificate of Registration Nos. CS23600, Respondent.	CASE NO.: 21-087-CS-N

ANSWER AND NOTICE OF DEFENSE

Pursuant to NRS 639.243(2) and NRS 639.244, Respondent Matthew M. Kikuchi [hereinafter "Answering Respondent"] by and through his attorneys, R. Christopher Reade, Esq. and the law firm of Cory Reade Dows and Shafer, and in response to Notice of Intended Action and Accusation, file this Answer and Notice of Defense as follows:

Answering Respondent objects to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him, is hereby interposed on the following grounds: Most if not all of the alleged accusations are barred by the applicable statue of limitation, including but not limited to, NRS 453.5533, NRS 11.220, and NRS 11.255. Additionally, these allegation may be barred by the equitable doctrine of laches, as the Board's decision to wait nearly eight years to allege these allegations has prejudiced Answering Respondent.

CORY READE DOWS & SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

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Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

JURISDICTION

1. Answering Paragraph 1 of the Complaint, Answering Respondent admit that Answering Plaintiff possess the license as described in Paragraph 1. Answering Respondent denies each and every remaining allegation therein.

2. Answering Paragraph 2 of the Complaint, Answering Respondent states that the Nevada Revised Statute speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the statute.

FACTUAL ALLEGATIONS

3. Answering Paragraphs 3 of the Complaint, Answering Respondent admits the allegations of this paragraph.

4. Answering Paragraphs 4 of the Complaint, Answering Respondent admits the allegations of this paragraph.

5. Answering Paragraphs 5 of the Complaint, Answering Respondent denies each and every allegation of this paragraph.

6. Answering Paragraph 6 of the Complaint, Answering Respondent denies each and every allegation of this paragraph.

7. Answering Paragraphs 7 of the Complaint, Answering Respondent admits that he had an active PMP account since 2016. Answering Respondent denies each and every remaining allegations of this Paragraph.

8. Answering Paragraphs 8 of the Complaint, Answering Respondent denies each and every other allegation contained therein.

9. Answering Paragraph 9 of the Complaint, Answering Respondent denies each and every other allegation contained therein.

APPLICABLE LAW

10. Answering Paragraphs 10 of the Complaint, states that the Nevada Revised Statute speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the statute.

11. Answering Paragraphs 11 of the Complaint, Answering Respondent states that the Nevada Revised Statute speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the statute.

12. Answering Paragraphs 12 of the Complaint, Answering Respondent states that the Nevada Revised Statute speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the statute.

13. Answering Paragraphs 13 of the Complaint, Answering Respondent states that the Nevada Administrative Code speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the Code.

14. Answering Paragraphs 14 of the Complaint, Answering Respondent d states that the Nevada Revised Statute speaks for itself. Answering Respondent denies each and every allegation therein which is inconsistent with the actual language of the statute.

COUNT ONE
(Unprofessional Conduct – Failure to Query PMP Every 6 Months)

15. Answering Paragraphs 15 of the Complaint, Answering Respondent admits that he established his PMP account on January 19, 2016. Answering Respondent denies each and every remaining allegation of this Paragraph.

16. Answering Paragraphs 16 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

17. Answering Paragraphs 17 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

18. Answering Paragraphs 18 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

CORY READE DOWS AND SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

COUNT TWO
(Unprofessional Conduct – Failure to Query PMP Prior to Issuing an Initial Prescription and/or Controlled Substance)

19. Answering Paragraphs 19 of the Complaint, A Answering Respondent admits that he established his PMP account on January 19, 2016. Answering Respondent denies each and every remaining allegation of this Paragraph.

20. Answering Paragraphs 20 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

21. Answering Paragraphs 21 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

22. Answering Paragraphs 22 of the Complaint, Answering Respondent denies each and every allegation of this Paragraph.

AFFIRMATIVE DEFENSES

1. The Complaint fails to state a claim warranting the relief for which it prays.

2. Relief is barred by the doctrine of waiver.

3. Relief is barred by the doctrine of estoppel.

4. The State cannot prove the necessary state of mind to warrant discipline.

5. The statutes and regulations the State seeks to enforce are void for vagueness facially and as applied.

6. The Complaint is barred by the applicable statute of limitations.

7. The Complaint is barred by the doctrine of laches.

8. The accusation fails to comply with NRS 639.241.

9. NRS 639.2576 is inapplicable to the accusation.

10. Answering Respondent reserves the right to add any defense warranted by discovery or evidence adduced at the hearing.

Wherefore, Respondent prays that the charges be dismissed and that the request for discipline be denied.

CORY READE DOWS AND SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

I declare under penalty of perjury the foregoing admissions, denials, averments, and defenses are true and correct to the best of my personal knowledge after diligent investigation. NRS 639.244(2).

DATED this 25th day of January, 2024.

CORY READE DOWS AND SHAFER

By: /s/ R. Christopher Reade

R. CHRISTOPHER READE
Nevada Bar No. 6791
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
Telephone: (702) 794-4411
Fax: (702) 794-4421
creade@crdslaw.com
Attorneys for Respondent

CORY READE DOWS AND SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

CERTIFICATE OF SERVICE

Pursuant to JCRCP 5(b), I certify that I am a representative of Cory Reade Dows & Shafer that on this 25th day of January, 2024, I caused the foregoing ANSWER AND NOTICE OF DEFENSE be served as follows:

- ☐ **NEFCR System upon the following All Parties in accordance with NEFCR 9 and 13:**
- ☐ **By First-Class United States Mail, postage prepaid upon the following Parties, for whom no compliance with the Electronic Service requirements has been undertaken:**
- ☐ **Personal Service upon the following parties or their Counsel:**
- ■ **By direct email upon the following Parties, for whom I did not receive, within a reasonable time indication that the transmission was unsuccessful:**
- ☐ **By fax or other electronic transmission in accordance with JCRCP 5(D) upon the following Parties, for which proof of successful transmission is attached hereto:**

TeamBC@Pharmacy.nv.gov	gvanderdonck@pharmacy.nv.gov

/s/ *Andrew M. David*
A Representative of Cory Reade Dows & Shafer

CORY READE DOWS AND SHAFER
1333 North Buffalo Drive, Suite 210
Las Vegas, Nevada 89128
(702) 794-4411 Fax (702) 794-4421

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MATTHEW M. KIKUCHI, DMD,** **Certificate of Registration No. CS23600,** **Respondent.**	**CASE NO. 21-087-CS-N** **STIPULATION AND ORDER**

Gustaf Vanderdonck, Assistant General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Matthew M. Kikuchi, Certificate of Registration No. CS23600, by and through counsel, R. Christopher Reade, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondent and this matter.

2. On or about January 5, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act);

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby freely and voluntarily waives their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter

622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act);

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Respondent failed to check the Prescription Monitoring Program (PMP) every six (6) months for the entire calendar years of 2016, 2017, 2018, 2019, 2020, despite issuing over 6,800 controlled substance prescriptions to unique patients in violation of NRS 453.164(7); NRS 639.210(4); and NAC 639.945(1)(i);

B. Respondent only conducted individual patient queries on two (2) patients between January 19, 2016, to April 4, 2023, despite issuing over 6,800 controlled substance prescriptions to unique patients in violation of NRS 639.23507; NRS 639.210(4); and NAC 639.945(1)(i);

7. These violations are pleaded with particularity in the Accusation and are grounds for action pursuant to NRS 639.210; NRS 639.255; NAC 639.945;

8. In order to resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties:

A. Respondent agrees to **continue to comply with all PMP related laws and regulations**, including but not limited to, NRS 453.164(7) and NRS 639.23507, and to contact the Board of Pharmacy in the future if he has any problems or questions;

B. Respondent shall pay a fine of **Six Thousand Five Hundred Dollars and Zero Cents ($6,500.00)** for the alleged violations, payable by *cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order;

C. Respondent shall pay **One Thousand Dollars and Zero Cents ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *certified check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) of the effective date of this Order;

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an Order to Show Cause pursuant to NAC 639.965 directing that Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. The Board may impose additional discipline upon Respondent consistent with the provisions of NRS Chapter 639;

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Respondent and/or Counsel for Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent is not present at the meeting;

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330;

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and agreement herein may not be used or referred to in a full hearing on the merits of this matter;

13. This matter will be reported to the National Practitioner Data Bank as required by 45 C.F.R. §§ 60.3; 60.5; and 60.9;

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts

set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 12 day of February, 2024

MATTHEW M. KIKUCHI, DMD;
Certificate of Registration No. CS23600

Signed this 14th day of February, 2024

GUSTAF A. VANDERDONCK, ESQ.
Assistant General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this 13 day of February, 2024

R. CHRISTOPHER READE, ESQ.
CORY, READE, DOWS & SHAFER
Counsel for Respondent

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Matthew M. Kikuchi, Certificate of Registration No. CS23600, in Case No. 21-087-CS-N and hereby orders that the terms of the foregoing Stipulation be made effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March, 2024.

_____

Helen Park, President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PLUS ONE PHARMACY, LLC,** **License No. PH04369,** **Respondents.**	**Case No. 21-189-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Plus One Pharmacy (Respondent), because Respondent, at the time of the violations alleged herein, held a License issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy. Since August 11, 2021, Respondent has held a license to operate a pharmacy issued by the Board pursuant to NRS 639.230.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent has been licensed by the Board to operate as a pharmacy since August 11, 2021. *See* NRS 639.230. Such a license authorizes the holder to conduct a pharmacy and to sell and dispense drugs and poisons and devices and appliances that are restricted by federal law to sale by or on the order of a physician. NRS 639.231.

4. Respondent Plus One Pharmacy, LLC is located at 6545 Fort Apache Road, #140, Las Vegas, NV 89148.

5. The owner of Respondent Plus One Pharmacy, LLC is Anisha Patel (Ms. Patel).

6. Ms. Patel is not herself licensed by the Board.

7. Ms. Patel is not a pharmacist.

8. On or about August 11, 2021, D.S. was listed as the managing pharmacist for Respondent.

9. On or about November 5, 2021, D.S. noticed a large shipment of drugs that had been delivered to Respondent.

10. These drugs were ordered and received without the managing pharmacist's knowledge.

11. None of the drugs were controlled substances; however, some of the drugs required refrigeration but were stored at room temperature. (i.e., insulin).

12. Once managing pharmacist D.S. discovered the drugs that were delivered without his knowledge, he immediately contacted Respondent's owner Ms. Patel and demanded that she turn over her pharmacy key to him.

13. Ms. Patel complied with the managing pharmacist's demand.

14. The drugs were then locked and secured and managing pharmacist D.S. verified that the inventory was accurate as stated on the invoice.

15. Ms. Patel stated that the unsupervised receipt of drugs by Respondent was due to a "miscommunication."

16. After verifying that the shipment of drugs was correctly documented on the accompanying invoices, managing pharmacist D.S. resigned and, being that Respondent did not have a managing pharmacist for the time being, the shipment of drugs was returned to the seller.

APPLICABLE LAW

17. In Nevada, the Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

18. Conduct contrary to the public interest includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

19. A pharmacy owner and managing pharmacist in charge of a licensed pharmacy shall maintain a representative stock of dangerous drugs and controlled substances which must be stored properly. NAC 639.510.

20. The security of the prescription department of a pharmacy must be maintained by a pharmacist, including key access. NAC 639.520

21. A pharmacist employed by the pharmacy shall acknowledge on every invoice that drugs shipped to the pharmacy were received at the address where the Board issued a pharmacy license. NAC 639.523.

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE
Conduct Contrary to the Public Interest in Receiving Drugs

23. Respondent, acting by and through Ms. Patel, ordered drugs and received them without a pharmacist present. A pharmacy owner and managing pharmacist in charge of a licensed pharmacy must maintain a representative stock of dangerous drugs and controlled substances. NAC 639.510. However, the stock of drugs must be acquired in the manner required by Nevada statutes and regulations.

24. More specifically, when shipments of drugs are received by a pharmacy, a pharmacist employed by the pharmacy must be there to acknowledge on each invoice that the drugs were received at the physical address where the Board issued the pharmacy license. NAC 639.523. Respondent's owner, Ms. Patel, stated that the absence of a pharmacist to receive the drug shipment was a "miscommunication."

25. As the holder of a pharmacy license issued by the Board, Respondent had a duty to receive dangerous drugs and controlled substances in the manner required by NAC 639.523. Acting by

and through Ms. Patel, Respondent performed this duty in an incompetent, unskillful, or negligent manner.

26. Through her actions as described above, Ms. Patel caused Respondent to engage in conduct contrary to the public interest. NRS 639.210(4). Respondent engaged in conduct contrary to the public interest because the pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

27. Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because it failed to ensure that a pharmacist employed by the pharmacy was present to receive the shipment of drugs. *See* NAC 639.523; and NAC 639.945(1)(i).

28. Having engaged in conduct contrary to the public interest as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT TWO
Conduct Contrary to the Public Interest in Allowing Access to Drugs

29. Respondent's owner Ms. Patel possessed a key to the pharmacy's prescription department despite not being a pharmacist. The security of the pharmacy's prescription department must be maintained by a pharmacist, including key access. NAC 639.520. Additional keys, not being handled by a pharmacist for the time being, must be secured in a manner that is inaccessible to unauthorized persons. NAC 639.520.

30. Because of her actions, Ms. Patel caused Respondent to engage in conduct contrary to the public interest. NRS 639.210(4). Respondent engaged in conduct contrary to the public interest because the pharmacy performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

31. Respondent performed its duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner because the pharmacy allowed other people, besides

registered pharmacists, key access into the pharmacy's prescription department. *See* NAC 639.520; and NAC 639.945(1)(i).

32. Having engaged in conduct contrary to the public interest as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 16th day of OCTOBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PLUS ONE PHARMACY, LLC,** **License No. PH04369,** **Respondents.**	**Case No. 21-189-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 6, 2023, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 18th day of OCTOBER, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PLUS ONE PHARMACY, LLC,** **License No. PH04369,** **Respondent.**	**Case No. 21-189-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR PLUS ONE PHARMACY, LLC

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 24th day of October, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. Mail to the following:

Plus One Pharmacy, LLC
6545 Fort Apache Rd #140
Las Vegas, NV 89148

SHIRLEY HUNTING

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MAURICE VARGAS, DDS,** **Certificate of Registration No. CS15506,** **Respondent.**	**CASE NO. 21-086-CS-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Maurice Vargas, D.D.S. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold a certificate of registration issued by the Board pursuant to NRS 453.226, authorizing Respondent to write prescriptions for controlled substances. Since August 31, 2007, Respondent has held certificate of registration no. CS15506, allowing Respondent to prescribe controlled substances issued by the Board pursuant to NRS 453.226.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent is a dentist who practices at North Vegas Dental, located at 1631 W. Craig Rd., North Las Vegas, NV 89032.

4. Respondent has been registered by the Board to prescribe controlled substances since August 31, 2007. NRS 453.226. Such a registration authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

5. A requirement of possessing a controlled substance registration with the Board is to maintain and actively use a prescription monitoring program (PMP) account. NRS 453.162.

6. Respondent's PMP account was activated on or about June 29, 2015.

7. Board PMP Compliance Coordinator Dave Jones conducts audits of practitioners to ensure that they are compliant with state law related to the PMP. The audits are conducted to ensure compliance with NRS 453.164(7) and NRS 639.23507.

8. Board PMP Compliance Coordinator Jones conducted an audit of Respondent's PMP account.

9. Board PMP Compliance Coordinator Jones found that Respondent conducted a "MyRx" review of all the prescriptions Respondent had written as required by NRS 453.164(7) on the following dates: June 26, 2023, May 17, 2023, June 13, 2022, February 21, 2022, June 14, 2021, June 18, 2019, June 29, 2017, and June 29, 2015.

10. Respondent was not in compliance for the entire calendar years of 2016, 2018, and 2020.

11. Additionally, Respondent was not in compliance for part of the calendar years of 2017, 2019, and 2021.

12. Board PMP Compliance Coordinator Jones also found that Respondent conducted individual patient queries a grand total of nine (9) times as required by NRS 639.23507, despite writing over 890 prescriptions for 651 unique patients during that period.

13. This means that Respondent failed to conduct individual patient inquires at least over 640 times during this period.

APPLICABLE LAW

14. Each practitioner who is authorized to write prescriptions for human consumption of controlled substances listed in schedule II, III, IV or V shall access the database of the (PMP) program at least once every 6 months to review the information concerning the practitioner that is listed in the database, including, without limitation, information concerning prescriptions issued by the practitioner, and notify the Board if any such information is not correct, and to verify to the Board that he or she

continues to have access to and has accessed the database as required by this subsection. NRS 453.164(7).

15. A practitioner shall, before issuing an initial prescription for a controlled substance listed in schedule II, III or IV or an opioid that is a controlled substance listed in schedule V and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the computerized program established by the Board. NRS 639.23507.

16. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

17. Unprofessional conduct includes, "performing any duties as the holder of a license issued by the Board in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

18. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Failure to Query PMP Every 6 Months

19. Respondent established his PMP account on June 29, 2015. Between these dates, Respondent failed to review his PMP account every six (6) months for the entire calendar years of 2016, 2018, and 2020 to ensure that the information in the account concerning the practitioner, including the legitimacy or validity of the prescriptions Respondent is shown as having written was correct. Respondent also failed to do this for part of the calendar years of 2017, 2019, and 2021. Respondent was and is still required to do so every six (6) months. NRS 453.164(7).

20. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

21. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to query his PMP account every six (6) months to review the information in the account regarding the practitioner as is required by law. *See* NRS 453.164(7) and NAC 639.945(1)(i). The information regarding the practitioner that Respondent was and still is required to look at includes information concerning the prescriptions written by the practitioner. *See* NRS 453.164(7). A check of the PMP account at least once every six (6) months ensures that a practitioner has not had their credentials stolen or duplicated and that, if they have been stolen or duplicated, the Board is notified of any potentially forged prescriptions by the practitioner in a timely manner. *See* NRS 453.164(7). The required six (6) month check of a practitioner's PMP account guards against forged controlled substance prescriptions and allows practitioners to work with the Board to stop them in real time. *See* NRS 453.164(7).

22. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

COUNT TWO

Unprofessional Conduct – Failure to Query Patients Prior to Issuing an Initial Prescription for a Controlled Substance

23. Between the period of time from January 1, 2018, to September 18, 2023, Respondent only queried individual patients given unique prescriptions nine (9) times. During the same period, Respondent wrote over 890 prescriptions for over 650 unique patients. Respondent failed to query the PMP regarding individual patient information when prescribing them controlled substances over 640 times.

24. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed his duties in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

25. Respondent performed his duties as the holder of a certificate of registration issued by the Board in an incompetent, unskillful or negligent manner because Respondent failed to conduct patient queries on over 640 patients given initial prescriptions for controlled substances in schedule I-IV, or for an opioid that is a controlled substance and listed in schedule V. *See* NRS 639.23507 and NAC 639.945(1)(i). Respondent failed to query over 640 patients that should have been queried as PMP records reflect that Respondent only queried nine patients since Respondent's PMP account has been active. *See* NRS 639.23507.

26. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MAURICE VARGAS, DDS,** **Certificate of Registration No. CS15506,** **Respondent.**	**CASE NO. 21-086-CS-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 6, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MAURICE VARGAS, DDS,** **Certificate of Registration No. CS15506,** **Respondent.**	**CASE NO. 21-086-CS-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2024.

_____

MAURICE VARGAS, DDS

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 26th day of January 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Maurice Vargas, DDS
[redacted] W. Craig RD #10
North Las Vegas, NV 89032

SHIRLEY HUNTING
BOARD COORDINATOR

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM, Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**Case No. 23-257-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Candice Denham, D.V.M. (Respondent), because the violations alleged herein, weigh on Respondent's character to hold certificates of registration issued by the Board pursuant to NRS 453.226 to prescribe controlled substances and NRS 639.100 to dispense drugs. Since April 19, 2023, Respondent has held certificate of registration number CS35349 to prescribe controlled substances issued by the Board pursuant to NRS 453.226 and certificate of registration number DV00822 to dispense drugs pursuant to NRS 639.100.

2. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines. NRS 639.070.

FACTUAL ALLEGATIONS

3. Respondent has been licensed by the Board to prescribe controlled substances (CS35349) since April 19, 2023. NRS 453.226. Such a license authorizes the holder to write prescriptions for controlled substances. NRS 453.226.

4. Respondent has been licensed by the Board to dispense drugs (DV00822) since April 19, 2023. NRS 639.100. Such a license authorizes the holder to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner. NRS 639.0065.

5. Respondent submitted a controlled substance application and an application for veterinary authority to dispense drugs, both signed on April 12, 2023, that stated she had never been the subject of a board citation or administrative action whether completed or pending in any state.

6. It later came to the Board's attention that Respondent had voluntarily surrendered her DEA Certificate of Registration No. FS5781263 in the State of Hawaii on February 24, 2023.

7. Respondent had admitted at the time to the DEA that she had been using stimulants.

8. On November 2, 2023, Respondent's controlled substance license was suspended pursuant to NRS 639.2107.

APPLICABLE LAW

9. If a regulatory body revokes the license of a person in a contested case pursuant to this chapter, the regulatory body shall prescribe a period during which the person may not apply for reinstatement of the license. The period must not be less than 1 year and not more than 10 years. NRS 622A.410(1).

10. The Board may suspend or revoke any registration if the holder or applicant is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

11. Unprofessional conduct includes, "performing or in any way being a party to any fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

12. The Board may suspend or revoke any registration if the holder or applicant has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent. NRS 639.2010(10).

13. The Board may revoke or suspend a registration if a respondent has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this

chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

14. A person may not secure or attempt to secure any certificate, license or permit issued by the Board for themselves by making, or causing to be made, any false representation. NRS 639.281(1).

15. In lieu of a suspension or revocation, or in concert with it, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE
Unprofessional Conduct by a DVM

16. Respondent applied for a certificate of registration with the Board to prescribe controlled substances pursuant to NRS 453.226. On the Board's controlled substance application, question three of section five asks whether the applicant has been the subject of a board citation or an administrative action whether completed or pending in any state. Respondent also applied for veterinarian authority to dispense drugs pursuant to NRS 639.100. On the Board's application for veterinarian authority to dispense drugs, question three of section four asks the same question, whether the applicant has been the subject of a board citation or administrative action whether completed or pending in any state. Respondent answered "no" to this question on both applications. Respondent answered "no" even though she had voluntarily surrendered her Hawaii DEA Registration Number FS 5781263 on February 24, 2023.

17. Because of these actions, Respondent has engaged in unprofessional conduct. NRS 639.210(4). Respondent engaged in unprofessional conduct because Respondent, as the holder of a certificate of registration issued by the Board, performed or was a party to a fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

18. Respondent performed or was a party to a fraudulent or deceitful practice or transaction because Respondent failed to disclose that she had voluntarily surrendered her Hawaii DEA Certificate of Registration. *See* NAC 639.945(1)(h). Respondent also performed or was a party to a fraudulent or deceitful practice or transaction because Respondent failed to truthfully answer question three of section five on the Board's controlled substance registration and question three of section four of the Board's application for veterinarian authority to dispense drugs. *See* NAC 639.945(1)(h).

19. Having engaged in unprofessional conduct as alleged above, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NRS 639.281; NAC 639.945; and NAC 639.955.

COUNT TWO

Obtaining a Certificate of Registration by the Filing of a False Application

20. Respondent filed a false application with the Board when her controlled substance application and her application for veterinary authority to dispense drugs neglected to disclose her voluntary surrender of her DEA Certificate of Registration.

21. The Board may suspend or revoke any registration if the holder or applicant has obtained any certificate, certification, license or permit by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent. NRS 639.2010(10). Additionally, a person may not secure or attempt to secure any certificate, license or permit issued by the Board for themselves by making, or causing to be made, any false representation. NRS 639.281(1).

22. Respondent's application was obtained by the filing of a false application because she neglected to disclose that she voluntarily surrendered her DEA certificate of registration less than two months before she sent in her applications to the Board. *See* NRS 639.210(10); NRS 639.281(1); and NRS 639.281(2).

23. Having obtained a certificate of registration from the Board by the filing of a false application, Respondent is subject to discipline by the Board. NRS 639.210(10); NRS 639.255; NRS 639.281; and NAC 639.955.

COUNT THREE
Violations of NRS Chapter 639

24. By filing an application with the Board that neglected to include Respondent's voluntary surrender of her DEA Certificate of Registration, she violated NRS 639.210(4), NRS 639.210(10), and NRS 639.281.

25. The Board may revoke or suspend a registration if a respondent has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

26. Respondent violated or attempted to violate provisions of NRS Chapter 639 when she failed to disclose to the Board that she voluntarily surrendered her DEA Certificate of Registration on February 24, 2023. *See* NRS 639.210(12).

27. These actions violated NRS 639.210(4) because she engaged in unprofessional conduct by being a party to a fraudulent or deceitful practice or transaction. *See* NRS 639.210(4); NRS 639.210(12); and NAC 639.945(1)(h). Respondent violated NRS 639.210(10) and NRS 639.281 because she obtained a certificate of registration from the Board by the filing of a false application. NRS 639.210(10); NRS 639.210(12); and NRS 639.281.

28. Having committed violations of NRS Chapter 639, Respondent is subject to discipline by the Board. NRS 639.210(4); NRS 639.210(10); NRS 639.210(12); NRS 639.255; NRS 639.281; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 14th day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM,** **Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**CASE NO. 23-257-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of NOVEMBER 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CANDICE DENHAM, DVM, Certificate of Registration Nos. CS35349, and DV00822,** **Respondent.**	**CASE NO. 23-257-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

CANDICE DENHAM, DVM

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of November 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Candice Denham, DVM
[redacted] West Elkhorn Rd
North Las Vegas, NV 89084

Candice Denham, DVM
[redacted] Emerald Cove Ct.
Las Vegas, NV 89117

SHIRLEY HUNTING

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. WALGREENS PHARMACY #05479, Pharmacy License No. PH01938, WALGREENS PHARMACY #02445, Pharmacy License No. PH01964, GRACE OPULENCIA, RPh., Pharmacist Registration No. 15190, Respondent.	Case Nos. 21-169-PH-S 21-169-PH-O 21-169-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #05479 ("Walgreens #05479"), because at the time of the events alleged herein, Respondent Walgreens #05479 held Pharmacy License No. PH01938, issued by the Board, pursuant to NRS 639.230, on May 20, 2005, which authorized Respondent Walgreens #05479 to operate a pharmacy within the State of Nevada.

2. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #02445 ("Walgreens #02445"), because at the time of the events alleged herein, Respondent Walgreens #002445 held Pharmacy License No. PH01964, issued by the Board, pursuant to NRS 639.230, on September 9, 2004, which authorized Respondent Walgreens #02445 to operate a pharmacy which dispenses into the State of Nevada.

3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE
(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

(Respondent Walgreens #02445)

6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

7. On or about April 10, 2019, Respondent Walgreens #02445, Certificate of Registration No. PH01964, entered into a Stipulation and Order Case No. 17-086-S. In the Stipulation, Respondent Walgreens admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employees who did not hold Nevada pharmacist registrations, had on three

separate occasions, overrode Drug Utilization Review ("DUR") warnings during the automatic refill data review of RX #1465131-04579. RX #1465131-04579 was written for Rophinirole 2mg, a treatment for restless leg syndrome, and incorrectly verified as Risperidone 2mg, an antipsychotic. Respondent Walgreens #02445 paid a fine of $2,000.00 and attorney's fees and costs of $1,000.00.

FACTUAL ALLEGATIONS

8. On or about October 14, 2021, the Board received a patient complaint indicating that the patient had incorrectly received preservative free single dose Methotrexate instead of the multidose Methotrexate containing a preservative.

9. Respondent Walgreens #05479 operated a pharmacy at 385 E. Silverado Ranch Blvd., Las Vegas, Nevada 89183 at the time of the events alleged herein.

10. Respondent Opulencia, RPh., was employed as a staff pharmacist at Walgreens #05479 at the time of the events alleged herein.

RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TwynBC@Pharmacy.nv.gov and p.keegan@harmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
Walgreens Pharmacy #05479

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
Las Vegas, NV 89183

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. WALGREENS PHARMACY #05479, Pharmacy License No. PH01938, WALGREENS PHARMACY #02445, Pharmacy License No. PH01964, GRACE OPULENCIA, RPh., Pharmacist Registration No. 15190, Respondent.	Case Nos. 21-169-PH-S 21-169-PH-O 21-169-RPH-S NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #05479 ("Walgreens #05479"), because at the time of the events alleged herein, Respondent Walgreens #05479 held Pharmacy License No. PH01938, issued by the Board, pursuant to NRS 639.230, on May 20, 2005, which authorized Respondent Walgreens #05479 to operate a pharmacy within the State of Nevada.

2. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #02445 ("Walgreens #02445"), because at the time of the events alleged herein, Respondent Walgreens #002445 held Pharmacy License No. PH01964, issued by the Board, pursuant to NRS 639.230, on September 9, 2004, which authorized Respondent Walgreens #02445 to operate a pharmacy which dispenses into the State of Nevada.

3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE
(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

(Respondent Walgreens #02445)

6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

7. On or about April 10, 2019, Respondent Walgreens #02445, Certificate of Registration No. PH01964, entered into a Stipulation and Order Case No. 17-086-S. In the Stipulation, Respondent Walgreens admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employees who did not hold Nevada pharmacist registrations, had on three

separate occasions, overrode Drug Utilization Review ("DUR") warnings during the automatic refill data review of RX #1465131-04579. RX #1465131-04579 was written for Rophinirole 2mg, a treatment for restless leg syndrome, and incorrectly verified as Risperidone 2mg, an antipsychotic. Respondent Walgreens #02445 paid a fine of $2,000.00 and attorney's fees and costs of $1,000.00.

FACTUAL ALLEGATIONS

8. On or about October 14, 2021, the Board received a patient complaint indicating that the patient had incorrectly received preservative free single dose Methotrexate instead of the multidose Methotrexate containing a preservative.

9. Respondent Walgreens #05479 operated a pharmacy at 385 E. Silverado Ranch Blvd., Las Vegas, Nevada 89183 at the time of the events alleged herein.

10. Respondent Opulencia, RPh., was employed as a staff pharmacist at Walgreens #05479 at the time of the events alleged herein.

RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

[redacted] and [redacted]

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
Walgreens Pharmacy #05479

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
Las Vegas, NV 89183

Darlene Nases
DARLENE NASES

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

WALGREENS PHARMACY #05479,
Pharmacy License No. PH01938,

WALGREENS PHARMACY #02445,
Pharmacy License No. PH01964,

GRACE OPULENCIA, RPh.,
Pharmacist Registration No. 15190,

Respondent.

Case Nos. 21-169-PH-S
21-169-PH-O
21-169-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #05479 ("Walgreens #05479"), because at the time of the events alleged herein, Respondent Walgreens #05479 held Pharmacy License No. PH01938, issued by the Board, pursuant to NRS 639.230, on May 20, 2005, which authorized Respondent Walgreens #05479 to operate a pharmacy within the State of Nevada.

2. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Walgreens Pharmacy #02445 ("Walgreens #02445"), because at the time of the events alleged herein, Respondent Walgreens #002445 held Pharmacy License No. PH01964, issued by the Board, pursuant to NRS 639.230, on September 9, 2004, which authorized Respondent Walgreens #02445 to operate a pharmacy which dispenses into the State of Nevada.

3. The Board has personal jurisdiction over Respondent Grace Opulencia, RPh. ("Opulencia"), because at the time of the events alleged herein, Respondent Opulencia held

Certificate of Registration No. 15190, issued by the Board, pursuant to NRS 639.127, on October 6, 2000, which authorized Respondent Opulencia to practice pharmacy in the State of Nevada.

4. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Opulencia was engaged in the practice of pharmacy at the pharmacy operated by Respondent Walgreens #05479 in the State of Nevada and Walgreens #02445 was operating a pharmacy which engaged in the practice of pharmacy into the State of Nevada.

PRIOR DISCIPLINE
(Respondent Opulencia)

5. On or about February 7, 2022, Respondent Opulencia was mailed a $500.00 Citation and Fine in Case No. 19-119-RPH-S for a medication misfill of Adderall XR capsules, 25mg wherein RX# 2969633 was short six capsules. Respondent Opulencia timely paid the $500.00 fine.

(Respondent Walgreens #02445)

6. In or about January of 2016, Respondent Walgreens #02445 a.k.a Walgreens Mail Service, Inc., Certificate of Registration No. PH01964, entered into a Stipulation and Order in Case No. 15-028-RPH-S. In the Stipulation, Respondent Walgreens #02445 admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employee, who did not hold a Nevada pharmacist registration, had incorrectly verified a RX #3094107-3922, a prescription written for Zoloft 200mg as simvastatin 20 mg tablets (generic Zocor). Respondent Walgreens #02445 paid a fine of $1,000.00 and attorney's fees and costs of $495.00.

7. On or about April 10, 2019, Respondent Walgreens #02445, Certificate of Registration No. PH01964, entered into a Stipulation and Order Case No. 17-086-S. In the Stipulation, Respondent Walgreens admitted it was responsible for the actions of its employees, pursuant to NAC 639.945(2), and that evidence existed to establish a factual basis demonstrating that its pharmacist employees who did not hold Nevada pharmacist registrations, had on three

separate occasions, overrode Drug Utilization Review ("DUR") warnings during the automatic refill data review of RX #1465131-04579. RX #1465131-04579 was written for Rophinirole 2mg, a treatment for restless leg syndrome, and incorrectly verified as Risperidone 2mg, an antipsychotic. Respondent Walgreens #02445 paid a fine of $2,000.00 and attorney's fees and costs of $1,000.00.

FACTUAL ALLEGATIONS

8. On or about October 14, 2021, the Board received a patient complaint indicating that the patient had incorrectly received preservative free single dose Methotrexate instead of the multidose Methotrexate containing a preservative.

9. Respondent Walgreens #05479 operated a pharmacy at 385 E. Silverado Ranch Blvd., Las Vegas, Nevada 89183 at the time of the events alleged herein.

10. Respondent Opulencia, RPh., was employed as a staff pharmacist at Walgreens #05479 at the time of the events alleged herein.

RX# 1930061-2

11. On or about August 2, 2021, Dana Shepherd, P.A. issued a prescription for "Methotrexate 50mg/2ml injection solution," with directions stating "0.5 milliliter inject subcutaneously one time weekly," and "#1 Bottle(s), 30-day, Refills: 2." The prescription was electronically transmitted to Respondent Walgreens #05479 and designated as RX# 1930061-2.

12. On or about August 3, 2021, pharmaceutical technician H.X. Jaghanan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the data entry for RX# 1930061-2. The data entry performed by H.X. Jaghanan identified prescription at "Methotrexate 25mg/ml PF SI."

13. Pharmaceutical technician H.X. Jaghanan is not licensed to practice pharmacy in the State of Nevada.

14. On or about August 23, 2021, pharmacist Julie Wan, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, performed the "Pat/Pbr rev" and "Data Product Review" for RX# 1930061-2.

15. Pharmacist Julie Wan is not licensed to practice pharmacy in the State of Nevada.

16. On or about August 23, 2021, pharmacist D. Pham, located at Walgreens #02445, at 8337 Southpark Circle, Orlando, Florida 32819, overrode 5 DURs for RX# 1930061-2.

17. Pharmacist D. Pham is not licensed to practice pharmacy in the State of Nevada.

18. On or about August 23, 2021, pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, who was located at Walgreens #05479, filled RX# 1930061-2.

19. On or about August 24, 2021, Respondent Opulencia performed the final verification and incorrectly verified RX# 1930061-2 as preservative free.

20. On or about August 26, 2021, RX# 1930061-2 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-2.

RX# 1930061-5 - REFILL

21. On or about September 28, 2021, Respondent Opulencia performed the final verification on a refill of RX# 1930061 and incorrectly verified the prescription as preservative free.

22. On or about September 28, 2021, RX# 1930061-5 was dispensed as a preservative free solution. Respondent Walgreen's #05479's computer system identified Respondent Opulencia as the pharmacist of record for RX# 1930061-5.

APPLICABLE LAW

23. A pharmacist, pharmacist intern, or dispensing practitioner shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness and, in making that determination, may consider, without limitation: (a) overutilization of the drug and drug

misuse; (b) underutilization of the drug; (c) therapeutic duplications, contradictions, and any warning labels or other information included with the drug; (d) interactions between the drug and any (i) other drugs which the patient is taking or has recently taken, (ii) diseases which the patient has, including any stages of the disease, and (iii) allergies that the patient may have; and (e) incorrect dosage or duration of treatment. NAC 639.707(4).

24. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder fails to strictly follow the instructions of a practitioner when filling, refilling, labeling, and dispensing a prescription. NAC 639.945(1)(d)

25. The Board may suspend or revoke any certificate, license, registration or permit for engaging in unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4), upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

26. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

27. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or

other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

28. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

29. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

30. If a pharmaceutical technician performs one of more of the functions necessary to prepare a prescription, the pharmacist supervising the pharmaceutical technician is responsible for the filled prescription, including but not limited to, verifying: (a) the selection and strength of the drug; the dosage form; and the labeling of the prescription. NAC 639.252(2).

31. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

32. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

33. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

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COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct
(Respondent Opulencia)

34. Respondent Opulencia's failure to accurately verify the prescription dosage and duration in strict conformance with the instructions of prescribing practitioner prior to dispensing dispense RX# 1930061-2 and RX# 1930061-5 violated NAC 639.707(4)(e) and constituted unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i). Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12) and/or NRS 639.255(3).

35. Respondent Opulencia, as the managing pharmacist of Walgreens #05479 at the time of the violations alleged herein, is responsible, pursuant to NRS 639.220(1), for the misfills of RX# 1930061-2 and RX# 1930061-5, including pursuant to NAC 639.252(2) and NAC 639.702, if the misfills were attributable to the unprofessional conduct, including incorrect prescription data entry by pharmaceutical technician J.N. Zuniga, or any of the other pharmacy employee of Walgreens #05479 under the supervision of Respondent Opulencia. Respondent Opulencia is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #05479)

36. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #05479, including Respondent Opulencia, or pharmaceutical technician J.N. Zuniga, Certificate of Registration No. PT24198, Walgreens #05479 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #05479 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

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COUNT THREE

Pharmacy/Pharmacy Owner Responsibility
(Respondent Walgreens #02445)

37. To the extent the dispensing errors on RX# 1930061-2 and RX# 1930061-5 were attributable to employees of Respondent Walgreens #02445, including pharmaceutical technician H.X. Jaghanan, pharmacist Julie Wan, or pharmacist D. Pham, Walgreens #02445 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Walgreens #02445 is therefore subject to discipline pursuant to NRS 639.210 and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TwynBC@Pharmacy.nv.gov and p.keegan@harmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24 day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WALGREENS PHARMACY #05479, Pharmacy License No. PH01938,** **Respondent.**	**Case No. 21-169-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
Walgreens Pharmacy #05479

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Walgreens Pharmacy #05479
385 E Silverado Ranch Blvd.
Las Vegas, NV 89183

Walgreens Pharmacy #02445
8337 S Park Circle
Orlando, FL 32819

William Stilling, Esq.
222 South Main St., Suite 500
Salt Lake City, UT 84101

Grace Opulencia, RPH
[redacted] Tamarus St.
Las Vegas, NV 89123

Grace Opulencia, RPH
[redacted] E Silverado Ranch Blvd.
Las Vegas, NV 89183

Darlene Nases
DARLENE NASES

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FILED
DEC - 8 2023
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES MARIUS AGRAVIO TOLENTINO, APRN, Certificate of Registration Nos. CS31227 (Inactive) - PR15600 (Inactive),** **Respondent.**	**Case No. 22-021-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Board has personal jurisdiction over Respondent James Marius Agravio Tolentino, APRN ("Tolentino"), because at the time of the events alleged herein, Respondent Tolentino held an active controlled substance registration, Certificate of Registration No. CS31227, issued by the Board, pursuant to NRS 639.127, on January 14, 2021, which authorized Respondent Tolentino to prescribe dangerous drugs and controlled substances in the State of Nevada.

2. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Tolentino was a practitioner engaged in the prescribing of dangerous drugs and/or controlled substances to Nevada patients.

FACTUAL ALLEGATIONS

3. On or about January 14, 2021, Respondent Tolentino was issued his initial Controlled Substance Registration, Certificate of Registration No. CS31227.

4. On or about May 13, 2022, the Board issued a cease-and-desist letter to Respondent Tolentino informing him that he was ineligible to hold a Nevada Controlled Substances Registration because his underlying Registered Nurse ("RN"), license number RN68993, and Advanced Practice Registered Nurse ("APRN-CNP"), license number 835286, had expired on or about February 4, 2022.

5. On or about May 19, 2022, Respondent Tolentino entered into a Stipulation with the Nevada State Board of Nursing, wherein his Nevada Professional Nurse license number RN68993 and Nevada Advanced Practice Registered Nurse license number 835286 were suspended. In the Stipulation, Respondent Tolentino freely admitted that:

> On September 6, 2017, the Board [of Nursing] accepted an Agreement for Monitoring that he had signed related to diverting controlled substances from his employer for his own personal use, a positive for cause drug test for Fentanyl, and for addiction to alcohol and/or controlled substances. The agreement included abstinence and drug testing stipulations. On February 1, 2022, Respondent reported to Board [of Nursing] staff that he had written multiple prescriptions for controlled substances in the name of a family member and had diverted the medications for his own personal use. . . . [H]e is addicted to alcohol and/or controlled substances.

6. Between June 2021 and January 2022, Respondent Tolentino prescribed Oxycodone-Acetaminophen 10-325 or Oxcontin ER 15 mg to his mother-in-law on twenty-two occasions without a bona fide therapeutic relationship or purpose, but for his own personal use.

7. Respondent Tolentino made a false statement on his application for a Nevada controlled substance registration dated November 25, 2020, when he failed to disclose the substance abuse Agreement for Monitoring he entered into with the Nevada State Board of Nursing on September 6, 2017.

APPLICABLE LAW

8. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to obtain possession of a controlled substance or a prescription for a controlled substance by

misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d); NRS 453.391(1); and/or 21 U.S.C. § 843(a)(3).

9. The Board shall register an applicant to dispense controlled substances included in schedules I to V, inclusive unless it determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research or industrial channels;
b. Compliance with state and local law;
c. Promotion of technical advances in the art of manufacturing controlled substances and the development of new substances;
d. Convictions of the applicant pursuant to laws of another country or federal or state laws relating to a controlled substance;
e. Past experience of the applicant in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion of controlled substances into other than legitimate medical, scientific research or industrial channels;
f. Furnishing by the applicant of false or fraudulent material in an application filed pursuant to the provisions of NRS 453.011 to 453.552, inclusive;
g. Suspension or revocation of the applicant's federal registration to manufacture, distribute, possess, administer or dispense controlled substances as authorized by federal law; and
h. Any other factors relevant to and consistent with the public health and safety.

NRS 453.231(1).

10. Diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest, pursuant to NAC 639.945(1)(g), and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. The Board may suspend or revoke a registration if the holder performs or in any way is a party to any fraudulent or deceitful practice or transaction because such actions constitute unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4) and NAC 639.945(1)(h), and/or NRS 453.236(1)(e).

12. Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct that is contrary to the public interest, pursuant to NAC 639.945(1)(n)(2), and is grounds for suspension or revocation of the any license or registration issued by the Board. NRS 639.210(4).

13. It is unlawful for a person knowingly to use of be under the influence of a controlled substance except in accordance with a lawfully issued prescription. NRS 453.411(1).

14. The Board may suspend or revoke any license or registration issued pursuant to NRS Chapter 639, and deny the application of any person for a certificate, license, registration, or permit, if the holder of applicant has a substance abuse disorder. NRS 639.210(5).

15. The Board may suspend or revoke any certificate, license, registration or permit upon a finding that the holder has willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provision of this chapter. NRS 639.210(9).

16. The Board may suspend or revoke and certificate, license, registration, or permit upon a finding that the holder has obtained the certificate, certification, license, or permit by the filing of an application, or any record, affidavit, or other information in support thereof, which is false or fraudulent. NRS 639.210(10).

17. It is unlawful for any person to secure registration by making, or causing to be made, any false representation. NRS 639.281(1). The Board may automatically cancel any certificate, license, or permit upon information later found to be false or fraudulent. NRS 639.281(2).

18. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. Administrative proceedings brought by the Board against a Respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257, and upon a finding of guilt against the Respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration of a schedule thereof. NRS 453.241.

21. The surrender, revocation or a suspension that has not been stayed of any certificate, license, or registration of a practitioner, as defined in NRS 453.126, 454.00958 or 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration, or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe, or dispense drugs. NRS 639.2107.

22. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

23. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(1)(f) and (3); NAC 639.955.

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COUNT ONE

Unlawful Prescribing, Diversion, Acquisition, and/or Use of Controlled Substance

24. By prescribing, diverting, acquiring and/or using controlled substances as alleged herein, Respondent Tolentino violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate 21 U.S.C. § 843(a)(3); and/or NRS 453.331(1)(d); and/or NRS 453.391(1); and/or NRS 453.411(1); and/or NRS 453.231(1) by acting outside the public interest. Therefore, Respondent Tolentino is subject to discipline pursuant to NRS 453.236(1)(e); and/or NRS 453.241; and/or NRS 639.210(4) and/or (11) and/or (12); and/or NRS 639.255(3).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

25. By prescribing controlled substances to his mother-in-law and diverting the controlled substances for personal use as alleged herein, Respondent Tolentino engaged deceitful practices and transactions and/or in unprofessional conduct and conduct contrary to the public interest, as defined by NAC 639.945(1)(h),(g), and (n)(2), which renders his continued registration to dispense controlled substances inconsistent with the public interest. Therefore, Respondent is subject to discipline pursuant to NRS 453.236(1)(e); and/or NRS 453.241(1); and/or NRS 639.210(4); and/or NRS 639.255.

COUNT THREE

False Statement on Application for Controlled Substance Registration

26. By making a false statement on his November 25, 2020, application for a Nevada Certificate of Registration to Dispense Controlled Substances, Respondent Tolentino violated NRS 639.210(10); and/or NRS 639.281(2); and/or NRS 453.231(1) by acting outside the public interest; therefore, Respondent is subject to discipline under NRS 639.210(10); and/or NRS 639.255(3); and/or NRS 639.281(2).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES MARIUS AGRAVIO TOLENTINO, APRN, Certificate of Registration Nos. CS31227 (Inactive) - PR15600 (Inactive),** **Respondent.**	**Case No. 22-021-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 8th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES MARIUS AGRAVIO TOLENTINO, APRN, Certificate of Registration Nos. CS31227 (Inactive) - PR15600 (Inactive),** **Respondent.**	**Case No. 22-021-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

JAMES MARIUS AGRAVIO TOLENTINO, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

John Marius Agravio Tolentino
[redacted]S. Green Valley Pkwy #300
Henderson, NV 89012

Darlene Nases
DARLENE NASES

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JOHN MARIUS AGRAVIO TOLENTINO, APRN, Certificate of Registration Nos. CS31227 (Inactive) - PR15600 (Inactive),** **Respondent.**	**Case No. 22-021-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through its General Counsel, Peter K. Keegan, Esq., and Respondent John Marius Agravio Tolentino ("Tolentino"), Certificate of Registration Nos. CS31227 (inactive) and PR15600 (inactive) **HEREBY STIPULATE AND AGREE AS FOLLOWS:**

1. On or about December 11, 2023, Board Staff served Tolentino with the Notice of Intended Action and Accusation ("Accusation") on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. In lieu of filing an Answer, Tolentino submits this Stipulation and Order for the Board's consideration.

3. Tolentino is aware of the right to seek the advice of counsel in this matter prior to entering this Stipulation.

4. Tolentino is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Tolentino has failed to comply with the provisions of this Stipulation, Tolentino hereby freely and voluntarily waives the right to a hearing, reconsideration,

appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

JURISDICTION

1. The Board has personal jurisdiction over Respondent James Marius Agravio Tolentino, APRN ("Tolentino"), because at the time of the events alleged herein, Respondent Tolentino held an active controlled substance registration, Certificate of Registration No. CS31227, issued by the Board, pursuant to NRS 639.127, on January 14, 2021, which authorized Respondent Tolentino to prescribe dangerous drugs and controlled substances in the State of Nevada.

2. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Tolentino was a practitioner engaged in the prescribing of dangerous drugs and/or controlled substances to Nevada patients.

FACTUAL ALLEGATIONS

3. On or about January 14, 2021, Respondent Tolentino was issued his initial Controlled Substance Registration, Certificate of Registration No. CS31227.

4. On or about May 13, 2022, the Board issued a cease-and-desist letter to Respondent Tolentino informing him that he was ineligible to hold a Nevada Controlled Substances Registration because his underlying Registered Nurse ("RN"), license number RN68993, and Advanced Practice Registered Nurse ("APRN-CNP"), license number 835286, had expired on or about February 4, 2022.

5. On or about May 19, 2022, Respondent Tolentino entered into a Stipulation with the Nevada State Board of Nursing, wherein his Nevada Professional Nurse license number RN68993 and Nevada Advanced Practice Registered Nurse license number 835286 were suspended. In the Stipulation, Respondent Tolentino freely admitted that:

> On September 6, 2017, the Board [of Nursing] accepted an Agreement for Monitoring that he had signed related to diverting controlled substances from his employer for his own personal use, a positive for cause drug test for Fentanyl, and for addiction to alcohol and/or controlled substances. The agreement included abstinence and drug testing stipulations. On February 1, 2022, Respondent reported to Board [of Nursing] staff that he had written

> multiple prescriptions for controlled substances in the name of a family member and had diverted the medications for his own personal use. . . . [H]e is addicted to alcohol and/or controlled substances.

6. Between June 2021 and January 2022, Respondent Tolentino prescribed Oxycodone-Acetaminophen 10-325 or OxyContin ER 15 mg to his mother-in-law on twenty-two occasions without a bona fide therapeutic relationship or purpose, but for his own personal use.

7. Respondent Tolentino made a false statement on his application for a Nevada controlled substance registration dated November 25, 2020, when he failed to disclose the substance abuse Agreement for Monitoring he entered into with the Nevada State Board of Nursing on September 6, 2017.

APPLICABLE LAW

8. It is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to obtain possession of a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 453.331(1)(d); NRS 453.391(1); and/or 21 U.S.C. § 843(a)(3).

9. The Board shall register an applicant to dispense controlled substances included in schedules I to V, inclusive unless it determines that the issuance of such registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

a. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, research or industrial channels;
b. Compliance with state and local law;
c. Promotion of technical advances in the art of manufacturing controlled substances and the development of new substances;
d. Convictions of the applicant pursuant to laws of another country or federal or state laws relating to a controlled substance;
e. Past experience of the applicant in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion of controlled substances into other than legitimate medical, scientific research or industrial channels;

f. Furnishing by the applicant of false or fraudulent material in an application filed pursuant to the provisions of NRS 453.011 to 453.552, inclusive;
g. Suspension or revocation of the applicant's federal registration to manufacture, distribute, possess, administer, or dispense controlled substances as authorized by federal law; and
h. Any other factors relevant to and consistent with the public health and safety.

NRS 453.231(1).

10. Diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest, pursuant to NAC 639.945(1)(g), and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. The Board may suspend or revoke a registration if the holder performs or in any way is a party to any fraudulent or deceitful practice or transaction because such actions constitute unprofessional conduct or conduct contrary to the public interest, pursuant to NRS 639.210(4) and NAC 639.945(1)(h), and/or NRS 453.236(1)(e).

12. Prescribing a drug as a prescribing practitioner to a patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct that is contrary to the public interest, pursuant to NAC 639.945(1)(n)(2), and is grounds for suspension or revocation of the any license or registration issued by the Board. NRS 639.210(4).

13. It is unlawful for a person knowingly to use of be under the influence of a controlled substance except in accordance with a lawfully issued prescription. NRS 453.411(1).

14. The Board may suspend or revoke any license or registration issued pursuant to NRS Chapter 639, and deny the application of any person for a certificate, license, registration, or permit, if the holder of applicant has a substance abuse disorder. NRS 639.210(5).

15. The Board may suspend or revoke any certificate, license, registration or permit upon a finding that the holder has willfully made to the Board or its authorized representative any false statement which is material to the administration or enforcement of any of the provision of this chapter. NRS 639.210(9).

16. The Board may suspend or revoke and certificate, license, registration, or permit upon a finding that the holder has obtained the certificate, certification, license, or permit by the filing of an application, or any record, affidavit, or other information in support thereof, which is false or fraudulent. NRS 639.210(10).

17. It is unlawful for any person to secure registration by making, or causing to be made, any false representation. NRS 639.281(1). The Board may automatically cancel any certificate, license, or permit upon information later found to be false or fraudulent. NRS 639.281(2).

18. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. Administrative proceedings brought by the Board against a Respondent pursuant to NRS Chapter 453, to deny, suspend or revoke a registration must be initiated, conducted and concluded pursuant to the provisions of NRS 639.241 to NRS 639.257, and upon a finding of guilt against the Respondent, the Board shall suspend the right of the registrant to use his or her registration or a schedule thereof; or revoke the registration of a schedule thereof. NRS 453.241.

21. The surrender, revocation or a suspension that has not been stayed of any certificate, license, or registration of a practitioner, as defined in NRS 453.126, 454.00958 or 639.0125, by a licensing board or the Drug Enforcement Administration operates as an immediate suspension of a certificate, license, registration, or permit issued by the Board pursuant to NRS chapters 453, 454 or 639 to possess, administer, prescribe, or dispense drugs. NRS 639.2107.

22. This Accusation constitutes a public record pursuant to NRS 622.330 and any discipline imposed by the Board shall be reported to the National Practitioner Data Bank as required by federal law. Title 42 USC § 1396r–2; 45 CFR Part 60.

23. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation alleged in an accusation for which the holder is found guilty. NRS 639.255(1)(f) and (3); NAC 639.955.

COUNT ONE

Unlawful Prescribing, Diversion, Acquisition, and/or Use of Controlled Substance

24. By prescribing, diverting, acquiring and/or using controlled substances as alleged herein, Respondent Tolentino violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate 21 U.S.C. § 843(a)(3); and/or NRS 453.331(1)(d); and/or NRS 453.391(1); and/or NRS 453.411(1); and/or NRS 453.231(1) by acting outside the public interest. Therefore, Respondent Tolentino is subject to discipline pursuant to NRS 453.236(1)(e); and/or NRS 453.241; and/or NRS 639.210(4) and/or (11) and/or (12); and/or NRS 639.255(3).

COUNT TWO

Commission of Acts that Render Registration Inconsistent with the Public Interest

25. By prescribing controlled substances to his mother-in-law and diverting the controlled substances for personal use as alleged herein, Respondent Tolentino engaged deceitful practices and transactions and/or in unprofessional conduct and conduct contrary to the public interest, as defined by NAC 639.945(1)(h),(g), and (n)(2), which renders his continued registration to dispense controlled substances inconsistent with the public interest. Therefore, Respondent is subject to discipline pursuant to NRS 453.236(1)(e); and/or NRS 453.241(1); and/or NRS 639.210(4); and/or NRS 639.255.

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COUNT THREE
False Statement on Application for Controlled Substance Registration

26. By making a false statement on his November 25, 2020, application for a Nevada Certificate of Registration to Dispense Controlled Substances, Respondent Tolentino violated NRS 639.210(10); and/or NRS 639.281(2); and/or NRS 453.231(1) by acting outside the public interest; therefore, Respondent is subject to discipline under NRS 639.210(10); and/or NRS 639.255(3); and/or NRS 639.281(2).

CULPABILITY
(Respondent Tolentino)

27. Tolentino admits the truth of each and every factual allegation in this Stipulation.

28. Tolentino admits the truth of the alleged violations of law in this Stipulation.

DISCIPLINARY ORDER

29. In consideration of the foregoing admissions and stipulations, and to save the time and expense of litigating the alleged violations of law before the Board, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

A. Tolentino's Certificate of Registration No. CS31227 is hereby revoked, Tolentino is prohibited from reapplying for a Certificate of Registration to Dispense Controlled Substances for a period of one (1) year to be measured from the effective date of the Board's Order accepting this Stipulation. Tolentino agrees that this one (1) year revocation constitutes formal discipline pursuant to NRS 233B.121(6) and that he shall comply with the below the below stipulation terms before reapplying to the Board; and

B. Tolentino shall comply with all the terms of the Nevada State Board of Nursing's Agreement for Suspension and Probation in Case No. 2022020005; and

C. Tolentino shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by way of a single *check, cashier's check* or *certified check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 not later than one (1) year or 365 days from effective date of the Board's Order; and

D. Tolentino shall pay Seven Hundred Fifty Dollars ($750.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, by *check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy**," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 within thirty (30) days of the effective date of this Order.

30. Any failure by Tolentino to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Tolentino to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Tolentino, the Board may impose additional discipline upon Tolentino consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

31. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2023. Tolentino will appear through its representatives and/or counsel at the meeting to answer questions from the Board Members. The Board Members may discuss and deliberate regarding this Stipulation, even if Tolentino is not present at the meeting.

32. The Board has discretion to accept this Stipulation, but it is not obligated to do so.

33. If the Board rejects any part or all this Stipulation, the parties agree that a full hearing on the merits of this matter may be heard by the Board – unless the parties reach an alternative agreement on the record which is approved by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

34. Subject to the approval of this Stipulation by the Board, the Board and Tolentino agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent Tolentino has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 31st date of January 2024.

JOHN M. A. TOLENTINO, APRN
Certificate of Registration Nos.
CS31227 (Inactive) & PR15600 (Inactive)

Signed this 31st date of January 2024.

PETER K. KEEGAN, ESQ.
General Counsel
Nevada State Board of Pharmacy

DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Respondent John Marius Agravio Tolentino, Certificate of Registration Nos. CS31227 (inactive) and PR15600 (inactive), in Case No. 22-021-CS-S and hereby orders that the terms of the foregoing Stipulation be made effective immediately upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WAL-MART PHARMACY #10-4239, Pharmacy License No. PH02772,** **Respondent.**	**Case No. 22-089-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy hereby files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent Wal-Mart Pharmacy #10-4239 ("Wal-Mart #10-4239"), because at the time of the events alleged herein, Respondent Wal-Mart #10-4239 held Pharmacy License No. PH02772, issued by the Board, pursuant to NRS 639.230, on February 13, 2012, which authorized Respondent Wal-Mart #10-4239 to operate a pharmacy within the State of Nevada.

2. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Wal-Mart #10-4239 was operating a pharmacy which dispensed dangerous drugs and controlled substances to Nevada patients.

FACTUAL ALLEGATIONS

3. At all times relevant to the allegations herein Respondent Wal-Mart #10-4239 operated a pharmacy located at 250 Vista Knoll Parkway, Reno, Nevada 89506. At all times relevant to the allegations herein, Respondent Wal-Mart #10-4239 employed pharmaceutical technician Junned Safdar and pharmacist Wencheng Liao.

4. On or about June 28, 2021, Dr. Devangi Desai prescribed a patient Metformin ER, 500mg tablets ASC, quantity 360, with instructions to take two tablets by mouth before breakfast and two tablets before evening meal. The prescription was tendered to Respondent Wal-Mart #10-4239 identified as RX# 7221879.

5. Respondent Wal-Mart #10-4239's records indicate that on or about January 22, 2022, RX# 7221879 was refilled by pharmaceutical technician Junned Safdar and visually verified by pharmacist Wencheng Liao (deceased) and dispensed to the patient. The patient was dispensed three white bottles containing the Ascend logo, two bottles correctly contained 100 tablets of Metformin Hydrochloride ER 500mg tablets AS, but one of the bottles incorrectly contained amlodipine besylate tablets, USP 5mg, quantity 500. Each of the three bottles contained a prescription label which specified RX# 7221879 and identified the drug as Metformin ER 500mg Tab ASC, quantity 360.

6. On or about January 22, 2022, the patient began ingesting the amlodipine besylate tablets, USP 5mg, and continued ingesting the medication for approximately two weeks.

7. The patient complained of disorientation, nausea, dizziness, and extreme fatigue; however, the patient did not seek medical treatment.

APPLICABLE LAW

8. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner, this includes failing to strictly following the instructions of a practitioner when filling, labeling, or dispensing a prescription. NAC 639.945(1)(d), (i).

9. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

10. The owner of any business of facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

11. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

12. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE

Unprofessional Conduct- Incompetent, Unskillful, or Negligent Conduct (Respondent Wal-Mart #10-4239)

13. The failure of Respondent Wal-Mart #10-4239's employees, pharmaceutical technician Junned Safdar and pharmacist Wencheng Liao (deceased), to accurately dispense RX# 7221879 in strict conformance with the instructions of prescribing practitioner constitutes unprofessional conduct and/or incompetent, unskillful, or negligent conduct contrary to the public interest pursuant to NAC 639.945(1)(d) and/or (i).

14. Wal-Mart #10-4239 is responsible for the unprofessional conduct of its employees pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(2). Respondent Wal-Mart #10-4239 is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of this Respondent Wal-Mart #10-4239.

Signed this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WAL-MART PHARMACY #10-4239, Pharmacy License No. PH02772,** **Respondent.**	**Case No. 22-089-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 6th day of December 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WAL-MART PHARMACY #10-4239, Pharmacy License No. PH02772,** **Respondent.**	**Case No. 22-089-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
Wal-Mart Pharmacy #10-4239

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of December, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Wal-Mart Pharmacy #10-4239
250 Vista Knoll Pkwy
Reno, NV 89506

Darlene Nases
DARLENE NASES

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **WAL-MART PHARMACY #10-4239, Pharmacy License No. PH02772,** **Respondent.**	**Case No. 22-089-PH-N** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (the "Board"), by and through its General Counsel, Peter K. Keegan, Esq., and Respondent, Wal-Mart Pharmacy #10-4239 ("Wal-Mart #10-4239"), Pharmacy License No. PH02772, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about December 11, 2023, Board staff served Wal-Mart #10-4239 with the Notice of Intended Action and Accusation ("Accusation") on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. In lieu of filing an Answer, Wal-Mart #10-4239 submits this Stipulation and Order for the Board's consideration.

3. Wal-Mart #10-4239 is aware of the right to seek the advice of counsel in this matter and has sought the advice of counsel prior to entering this Stipulation.

4. Wal-Mart #10-4239 is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Wal-Mart #10-4239 has failed to comply with the provisions of this Stipulation, Wal-Mart #10-4239 hereby freely and voluntarily waives its rights

to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to it by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

JURISDICTION

6. The Board has personal jurisdiction over Wal-Mart #10-4239 because at the time of the events alleged herein, Wal-Mart #10-4239 held Pharmacy License No. PH02772, issued by the Board, pursuant to NRS 639.230, on February 13, 2012, which authorized Wal-Mart #10-4239 to operate a pharmacy within the State of Nevada.

7. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Wal-Mart #10-4239 was operating a pharmacy which dispensed dangerous drugs and controlled substances to Nevada patients.

FACTUAL ALLEGATIONS

8. At all times relevant to the allegations herein Wal-Mart #10-4239 operated a pharmacy located at 250 Vista Knoll Parkway, Reno, Nevada 89506. At all times relevant to the allegations herein, Wal-Mart #10-4239 employed pharmaceutical technician Junned Safdar and pharmacist Wencheng Liao.

9. On or about June 28, 2021, Dr. Devangi Desai prescribed a patient Metformin ER, 500mg tablets ASC, quantity 360, with instructions to take two tablets by mouth before breakfast and two tablets before evening meal. The prescription was tendered to Wal-Mart #10-4239 identified as RX# 7221879.

10. Wal-Mart #10-4239's records indicate that on or about January 22, 2022, RX# 7221879 was refilled by pharmaceutical technician Junned Safdar and visually verified by pharmacist Wencheng Liao (deceased) and dispensed to the patient. The patient was dispensed three white bottles containing the Ascend logo, two bottles correctly contained 100 tablets of Metformin Hydrochloride ER 500mg tablets AS, but one of the bottles incorrectly contained amlodipine

besylate tablets, USP 5mg, quantity 500. Each of the three bottles contained a prescription label which specified RX# 7221879 and identified the drug as Metformin ER 500mg Tab ASC, quantity 360.

11. On or about January 22, 2022, the patient began ingesting the amlodipine besylate tablets, USP 5mg, and continued ingesting the medication for approximately two weeks.

12. The patient complained of disorientation, nausea, dizziness, and extreme fatigue; however, the patient did not seek medical treatment.

APPLICABLE LAW

13. Wal-Mart #10-4239 admits that evidence exists, and that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for certain of the violations alleged in the Accusation, *to wit*:

A. As the pharmacy/pharmacy owner, Wal-Mart #10-4239 is responsible for the unprofessional conduct of its employees pursuant to NRS 639.230(5), NAC 639.702, and NAC 639.945(3). Wal-Mart # 10-4239 is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

AGREEMENT

14. In consideration of the foregoing stipulations, and to save the time and expense of litigating the alleged violations of law before the Board, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

A. Wal-Mart #10-4239 shall pay a fine of One Thousand Dollars ($1,000.00) for the violations, by *check, cashier's check* or *certified check* or *money order* made payable to "**State of Nevada, Office of the Treasurer**," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 within thirty (30) days of the effective date of this Order; and

B. Wal-Mart #10-4239 shall pay Seven Hundred Fifty Dollars ($750.00) to partially reimburse the Board for recoverable attorney's fees and costs incurred in

investigating and prosecuting this matter, by *check, cashier's check* or *certified check* or *money order* made payable to "**Nevada State Board of Pharmacy**," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521 within thirty (30) days of the effective date of this Order.

15. Any failure by Wal-Mart #10-4239 to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Wal-Mart #10-4239 to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Wal-Mart #10-4239, the Board may impose additional discipline upon Wal-Mart #10-4239 consistent with the provisions of NRS Chapter 453 and/or Chapter 639.

16. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on March 6, 2024. Wal-Mart #10-4239 will appear through its representatives and/or counsel at the meeting to answer questions from the Board Members. The Board Members may discuss and deliberate regarding this Stipulation, even if Wal-Mart #10-4239 is not present at the meeting.

17. The Board has discretion to accept this Stipulation, but it is not obligated to do so.

18. If the Board rejects any part or all of this Stipulation, and unless the parties reach an alternative agreement on the record which is approved by the Board, the parties agree that a full hearing on the merits of this matter may be held at the next regularly scheduled Board meeting in Las Vegas. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing on the merits of this matter.

19. Subject to the approval of this Stipulation by the Board, the Board and Wal-Mart #10-4239 agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Wal-Mart #10-4239 has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 20 date of February 2024.

RESPONDENT

Shelley Tustison

Wal-Mart Pharmacy #10-4239
Pharmacy License No. PH02772

By: Shelley Tustison

Its: Sr. Director Practice Compliance

APPROVED AS TO FORM AND CONTENT this ___ day of February 2024.

STILLING & HARRISON, PLLC

William Stilling, Esq.
Nevada Bar No. 9915
222 S. Main St.
Salt Lake City, UT
(801) 341-2021
Counsel for Respondent

Signed this 20th date of February 2024.

NEVADA STATE BOARD OF PHARMACY

PETER K. KEEGAN, ESQ.
General Counsel
Nevada Bar No. 12237
985 Damonte Ranch Pkwy, Suite 206
Reno, Nevada 89521
775-850-1440

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DECISION AND ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its decision as to Wal-Mart #10-4239, Pharmacy License No. PH02772, in Case No. 22-089-PH-N and hereby orders that the terms of the foregoing Stipulation be made effective immediately upon execution below.

IT IS SO ORDERED.

Entered this ___ day of March 2024.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CVS PHARMACY #8821
Pharmacy License No. PH01095,

EUGENE BONDOC NAVAL, RPh.,
Certificate of Registration No. 19578,

Respondents.

Case Nos. 23-126-PH-S
23-126-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent CVS Pharmacy #8821 ("CVS #8821"), because at the time of the events alleged herein, Respondent CVS #8821 held Pharmacy License No. PH01095, issued by the Board, pursuant to NRS 639.230, on November 14, 1996, which authorized Respondent CVS #8821 to operate a pharmacy within the State of Nevada.

2. The Board has personal jurisdiction over Respondent Eugen Bondoc Naval, RPh. ("Naval"), because at the time of the events alleged herein, Respondent Naval held Certificate of Registration No. 19578, issued by the Board, pursuant to NRS 639.127, on May 23, 2017, which authorized Respondent Naval to practice pharmacy in the State of Nevada.

3. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Naval was engaged in the practice of pharmacy at the pharmacy operated by Respondent CVS #8821 in the State of Nevada.

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FACTUAL ALLEGATIONS

4. On or about April 5, 2023, the Board received a complaint concerning the pharmaceutical technician ratio CVS #8821.

5. Respondent CVS #8821 operated a pharmacy at 8320 W. Cheyenne Avenue, Las Vegas, Nevada 89129 at the time of the events alleged herein.

6. Respondent Eugene Naval, RPh., was employed as the managing pharmacist at CVS #8821 at the time of the events alleged herein.

7. On or about April 19, 2023, the Board's inspector conducted a site visit and inspection of Respondent CVS #8821.

8. During the April 19, 2023, inspection of Respondent CVS #8821's pharmacy, the Board's inspector observed Respondent Eugene Naval working in the pharmacy as the managing pharmacist along with five (5) additional people who identified themselves as pharmaceutical technicians and who were signed in as pharmacy technicians.

9. Respondent CVS #8821's sign in logs reflected a pharmacist to pharmaceutical technician ratio for exceeding one to three on the following dates:

i. April 18, 2023 – one pharmacist to four pharmaceutical technicians;

ii. April 17, 2023 – one pharmacist to four pharmaceutical technicians;

iii. April 14, 2023 – one pharmacist to four pharmaceutical technicians; and

iv. April 10, 2023 – one pharmacist to four pharmaceutical technicians.

10. Respondent CVS #8821 conducts pharmaceutical technician employee scheduling through a computerized system which is pre-populated by CVS corporate based upon anticipated customer demand.

11. On at least five dates, Respondent CVS #8821 exceeded Nevada's pharmacist to pharmaceutical technician supervision ratio of one to three.

12. On at least five dates, Respondent Naval failed to supervise the pharmaceutical technician ratio at CVS #8821.

APPLICABLE LAW

15. A pharmacist working in a dispensing pharmacy may supervise no more than three pharmaceutical technicians. NRS 639.1371(1); NAC 639.250(2).

16. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

17. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

19. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

20. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

21. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

22. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

23. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE

Exceeding the Supervising Pharmacist to Pharmaceutical Technician Ratio
(Respondents Naval)

24. Respondent Naval, as the managing pharmacist of CVS #8821 at the time of the events alleged herein, violated NAC 639.250(2) by exceeding the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. Pursuant to NRS 639.220(1) and NAC 639.702, Respondent Naval is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy. Respondent Navel is therefore subject to discipline pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3).

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COUNT TWO

Exceeding the Supervising Pharmacist to Pharmaceutical Technician Ratio
(Respondents CVS #8821)

25. Respondent CVS #8821 violated NAC 639.250(2) by scheduling employees in excess of the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. Respondent CVS #8821 is therefore subject to discipline pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3). Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), CVS #8821 is also subject to discipline, pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3), as the pharmacy owner responsible for the acts of its managing pharmacist and the employees supervised thereby.

COUNT THREE

Unprofessional Conduct
(Respondents Naval)

26. Respondent Naval, as the managing pharmacist of CVS #8821 at the time of the events alleged herein, is responsible, pursuant to NRS 639.220(1), and/or NAC 639.702 for allowing the pharmacist to pharmaceutical technician ratio to exceed one to three in violation of NAC 639.250 on five dates. This constituted unprofessional conduct, as defined in NAC 639.945(1)(i). Respondent Naval is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT FOUR

Unprofessional Conduct
(Respondents CVS #8821)

27. Respondent CVS #8821, engaged in unprofessional conduct by scheduling employees in excess of the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. This constituted unprofessional conduct, as defined in NAC 639.945(1)(i) and Respondent CVS #8821 is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3). Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), CVS #8821 is also subject to discipline, pursuant to NRS 639.210(4) and/or NRS 639.255(3), as the pharmacy owner responsible for the acts of its managing pharmacist and the employees supervised thereby.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 16th day of November 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8821** **Pharmacy License No. PH01095,** **Respondent.**	**Case No. 23-126-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 16th day of November, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8821** **Pharmacy License No. PH01095,** **Respondent.**	**Case No. 23-126-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

TYPE OR PRINT NAME

_____

AUTHORIZED REPRESENTATIVE FOR
CVS Pharmacy #8821

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of November, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Eugene Naval, RPH
[redacted] Azure Jay Ave.
North Las Vegas, NV 89084

Eugene Naval, RPH
[redacted] W. Cheyenne Ave.
Las Vegas, NV 89128

CVS/PHARMACY #8821
8320 W. Cheyenne Ave.
Las Vegas, NV 89128

Brian Convery, Esq.
200 Campus Drive, Suite 310
Florham Park, NJ 07932

Darlene Nases

DARLENE NASES

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

CVS PHARMACY #8821
Pharmacy License No. PH01095,

EUGENE BONDOC NAVAL, RPh.,
Certificate of Registration No. 19578,

Respondents.

Case Nos. 23-126-PH-S
23-126-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has personal jurisdiction over Respondent CVS Pharmacy #8821 ("CVS #8821"), because at the time of the events alleged herein, Respondent CVS #8821 held Pharmacy License No. PH01095, issued by the Board, pursuant to NRS 639.230, on November 14, 1996, which authorized Respondent CVS #8821 to operate a pharmacy within the State of Nevada.

2. The Board has personal jurisdiction over Respondent Eugen Bondoc Naval, RPh. ("Naval"), because at the time of the events alleged herein, Respondent Naval held Certificate of Registration No. 19578, issued by the Board, pursuant to NRS 639.127, on May 23, 2017, which authorized Respondent Naval to practice pharmacy in the State of Nevada.

3. The Board has subject matter jurisdiction over this matter because at the time of the events alleged herein Respondent Naval was engaged in the practice of pharmacy at the pharmacy operated by Respondent CVS #8821 in the State of Nevada.

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FACTUAL ALLEGATIONS

4. On or about April 5, 2023, the Board received a complaint concerning the pharmaceutical technician ratio CVS #8821.

5. Respondent CVS #8821 operated a pharmacy at 8320 W. Cheyenne Avenue, Las Vegas, Nevada 89129 at the time of the events alleged herein.

6. Respondent Eugene Naval, RPh., was employed as the managing pharmacist at CVS #8821 at the time of the events alleged herein.

7. On or about April 19, 2023, the Board's inspector conducted a site visit and inspection of Respondent CVS #8821.

8. During the April 19, 2023, inspection of Respondent CVS #8821's pharmacy, the Board's inspector observed Respondent Eugene Naval working in the pharmacy as the managing pharmacist along with five (5) additional people who identified themselves as pharmaceutical technicians and who were signed in as pharmacy technicians.

9. Respondent CVS #8821's sign in logs reflected a pharmacist to pharmaceutical technician ratio for exceeding one to three on the following dates:

i. April 18, 2023 – one pharmacist to four pharmaceutical technicians;

ii. April 17, 2023 – one pharmacist to four pharmaceutical technicians;

iii. April 14, 2023 – one pharmacist to four pharmaceutical technicians; and

iv. April 10, 2023 – one pharmacist to four pharmaceutical technicians.

10. Respondent CVS #8821 conducts pharmaceutical technician employee scheduling through a computerized system which is pre-populated by CVS corporate based upon anticipated customer demand.

11. On at least five dates, Respondent CVS #8821 exceeded Nevada's pharmacist to pharmaceutical technician supervision ratio of one to three.

12. On at least five dates, Respondent Naval failed to supervise the pharmaceutical technician ratio at CVS #8821.

APPLICABLE LAW

15. A pharmacist working in a dispensing pharmacy may supervise no more than three pharmaceutical technicians. NRS 639.1371(1); NAC 639.250(2).

16. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(4) upon a finding that the holder performed his or her duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner. NAC 639.945(1)(i).

17. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(12) upon the finding that the holder, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. The Board may suspend or revoke any certificate, license, registration or permit pursuant to NRS 639.210(15) upon the finding that the holder, as a managing pharmacist, violated any provision of law or regulation concerning recordkeeping or inventory in a store over which he or she presides, or has knowingly allowed a violation of any provision of NRS Chapter 639 or other state or federal laws or regulations relating to the practice of pharmacy by personnel of the pharmacy under his or her supervision.

19. Each pharmacy must be managed by a registered pharmacist, approved by the Board, who is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.220(1).

20. Any violation of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy under the supervision of the managing pharmacist is cause for suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5).

21. The owner of any business or facility licensed, certified, or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(2).

22. The owner of a pharmacy, the managing pharmacist of the pharmacy and the registered pharmacist on duty are responsible for the acts and omissions of pharmaceutical technicians and other personnel who are not pharmacists working in or for the pharmacy, including, but not limited to, any errors committed or unauthorized work performed by such personnel, if the owner, managing pharmacist or registered pharmacist knew or reasonably should have known of the act or omission. NAC 639.702.

23. The Board may impose a fine upon the holder of a certificate, license, or permit issued by the Board for up to $10,000.00 for each violation. NRS 639.255(3).

COUNT ONE

Exceeding the Supervising Pharmacist to Pharmaceutical Technician Ratio
(Respondents Naval)

24. Respondent Naval, as the managing pharmacist of CVS #8821 at the time of the events alleged herein, violated NAC 639.250(2) by exceeding the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. Pursuant to NRS 639.220(1) and NAC 639.702, Respondent Naval is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy. Respondent Navel is therefore subject to discipline pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3).

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COUNT TWO

Exceeding the Supervising Pharmacist to Pharmaceutical Technician Ratio
(Respondents CVS #8821)

25. Respondent CVS #8821 violated NAC 639.250(2) by scheduling employees in excess of the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. Respondent CVS #8821 is therefore subject to discipline pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3). Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), CVS #8821 is also subject to discipline, pursuant to NRS 639.210(12); and/or NRS 639.210(15); and/or NRS 639.255(3), as the pharmacy owner responsible for the acts of its managing pharmacist and the employees supervised thereby.

COUNT THREE

Unprofessional Conduct
(Respondents Naval)

26. Respondent Naval, as the managing pharmacist of CVS #8821 at the time of the events alleged herein, is responsible, pursuant to NRS 639.220(1), and/or NAC 639.702 for allowing the pharmacist to pharmaceutical technician ratio to exceed one to three in violation of NAC 639.250 on five dates. This constituted unprofessional conduct, as defined in NAC 639.945(1)(i). Respondent Naval is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3).

COUNT FOUR

Unprofessional Conduct
(Respondents CVS #8821)

27. Respondent CVS #8821, engaged in unprofessional conduct by scheduling employees in excess of the allowable pharmacist to pharmaceutical technician ratio on five (5) dates. This constituted unprofessional conduct, as defined in NAC 639.945(1)(i) and Respondent CVS #8821 is therefore subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.255(3). Pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2), CVS #8821 is also subject to discipline, pursuant to NRS 639.210(4) and/or NRS 639.255(3), as the pharmacy owner responsible for the acts of its managing pharmacist and the employees supervised thereby.

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

Signed this 16th day of November 2023.

J. David Wuest, R.Ph., Executive Secretary,
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **EUGENE BONDOC NAVAL, RPh., Certificate of Registration No. 19578,** **Respondent.**	**Case No. 23-126-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 17, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and p.keegan@pharmacy.nv.gov

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 16th day of NOVEMBER, 2023.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **EUGENE BONDOC NAVAL, RPh., Certificate of Registration No. 19578,** **Respondent.**	**Case No. 23-126-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____, 2023.

_____

EUGENE BONDOC NAVAL, RPh.,

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 27th day of November, 2023, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Eugene Naval, RPH
[redacted] Azure Jay Ave.
North Las Vegas, NV 89084

Eugene Naval, RPH
[redacted] W. Cheyenne Ave.
Las Vegas, NV 89128

CVS/PHARMACY #8821
8320 W. Cheyenne Ave.
Las Vegas, NV 89128

Brian Convery, Esq.
200 Campus Drive, Suite 310
Florham Park, NJ 07932

Darlene Naser
DARLENE NASES

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☑ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Sunrise Respiratory Care, Inc.

MDEG Physical Address: 6340 McLeod Rd #8

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Telephone: 949 398-6555 Website: www.sunriseresp.com

Email: management@sunriseresp.com

Name of MDEG Administrator (NAC 639.694): Craig Sherman

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☑ Patients by prescriptions	☑ Medical Gases**
☐ Pharmacies[a]	☑ Respiratory Equipment**
☐ Practitioners[a]	☑ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☑ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Craig Sherman
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8:30-5:00	■ Tue: 8:30-5:00	■ Wed: 8:30-5:00	■ Thurs: 8:30-5:00	■ Fri: 8:30-5:00
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN: 6667640001
MediCal: 800659606
NPI: 1255632394; 1114610045; 1831961929; 1740802610

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: ** Ownership has no healthcare licensure in Nevada Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California (also registered in Nevada, Texas, Arizona)

Parent Company (if any): _____

Corporation/Organization Name: Sunrise Respiratory Care, Inc.

Mailing Address: 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Telephone: 949 398 6555 Email: Nevada@sunriseresp.com

Contact Person Name: Craig Sherman

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Eilbert

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/25/2023

Date

Board Use Only	Date Received	Amount

Sunrise Respiratory Care, Inc.
List of Officers and Directors

Officers

CEO	Oscar Munoz
CFO	Michael Eilbert
Secretary	Michael Eilbert

Board of Directors:
Oscar Munoz
Michael Eilbert

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SUNRISE RESPIRATORY CARE, INC.
Entity No.:	3317090
Registration Date:	09/01/2010
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 17, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 130109725

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

SUNRRES-01 2912 CMEKSAVANH

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/1/2023

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER License # 0C36861
Irvine-Alliant Insurance Services, Inc.
18100 Von Karman Ave 10th Fl
Irvine, CA 92612

CONTACT NAME: Carla Meksavanh
PHONE (A/C, No, Ext): (619) 361-5582 FAX (A/C, No):
E-MAIL ADDRESS: Carla.Meksavanh@alliant.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Massachusetts Bay Insurance Company	22306
INSURER B : Allmerica Financial Benefit Insurance Company	41840
INSURER C : Hanover Insurance Company	22292
INSURER D : Hanover American Insurance Company	36064
INSURER E :	
INSURER F :	

INSURED
Sunrise Respiratory Care, Inc.
6340 McLeod Dr., #8
Las Vegas, NV 89120

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$	1,000,000
	CLAIMS-MADE X OCCUR	X	X	LD3H656305	7/11/2023	7/11/2024	DAMAGE TO RENTED PREMISES (Ea occurrence)	$	100,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	3,000,000
	OTHER						PROFESSIONAL LI	$	Included
B	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO			AW3H683755	7/11/2023	7/11/2024	BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
C	X UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$	2,000,000
	EXCESS LIAB CLAIMS-MADE			UH3H656307	7/11/2023	7/11/2024	AGGREGATE	$	
	DED X RETENTION $ 0						General Agg	$	2,000,000
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N / A		WM3H943412	7/11/2023	7/11/2024	E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
McLeod 5, LLC, a Nevada Limited Liability Company and Ribeiro Management Company, LLC dba The Ribeiro Company are included as Additional Insured under General Liability as per attached policy forms. Waiver of Subrogation applied under General Liability as per attached policy forms. 30 day notice of cancellation in favor of certificate holder

CERTIFICATE HOLDER

McLeod 5, LLC, a Nevada Limited Liability Company
Ribeiro Management Company, LLC dba The Ribeiro Compan
195 E. Reno Ave. #A
Las Vegas, NV 89119

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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THIS ENDORSEMENT CHANGES THE POLICY. PLEASE READ IT CAREFULLY.

COMMERCIAL GENERAL LIABILITY BROADENING ENDORSEMENT

This endorsement modifies insurance provided under the following:

COMMERCIAL GENERAL LIABILITY COVERAGE PART

SUMMARY OF COVERAGES

1.	Additional Insured by Contract, Agreement or Permit	Included
2.	Additional Insured – Primary and Non-Contributory	Included
3.	Blanket Waiver of Subrogation	Included
4.	Bodily Injury Redefined	Included
5.	Broad Form Property Damage – Borrowed Equipment, Customers Goods & Use of Elevators	Included
6.	Knowledge of Occurrence	Included
7.	Liberalization Clause	Included
8.	Medical Payments – Extended Reporting Period	Included
9.	Newly Acquired or Formed Organizations - Covered until end of policy period	Included
10.	Non-owned Watercraft	51 ft.
11.	Supplementary Payments Increased Limits	
	- Bail Bonds	$2,500
	- Loss of Earnings	$1000
12.	Unintentional Failure to Disclose Hazards	Included
13.	Unintentional Failure to Notify	Included

This endorsement amends coverages provided under the Commercial General Liability Coverage Part through new coverages, higher limits and broader coverage grants.

1. Additional Insured by Contract, Agreement or Permit

The following is added to **SECTION II – WHO IS AN INSURED:**

Additional Insured by Contract, Agreement or Permit

a. Any person or organization with whom you agreed in a written contract, written agreement or permit that such person or organization to add an additional insured on your policy is an additional insured only with respect to liability for "bodily injury", "property damage", or "personal and advertising injury" caused, in whole or in part, by your acts or omissions, or the acts or omissions of those acting on your behalf, but only with respect to:

(1) "Your work" for the additional insured(s) designated in the contract, agreement or permit;

(2) Premises you own, rent, lease or occupy; or

(3) Your maintenance, operation or use of equipment leased to you.

b. The insurance afforded to such additional insured described above:

(1) Only applies to the extent permitted by law; and

(2) Will not be broader than the insurance which you are required by the contract, agreement or permit to provide for such additional insured.

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(3) Applies on a primary basis if that is required by the written contract, written agreement or permit.

(4) Will not be broader than coverage provided to any other insured.

(5) Does not apply if the "bodily injury", "property damage" or "personal and advertising injury" is otherwise excluded from coverage under this Coverage Part, including any endorsements thereto.

c. This provision does not apply:

(1) Unless the written contract or written agreement was executed or permit was issued prior to the "bodily injury", "property damage", or "personal injury and advertising injury".

(2) To any person or organization included as an insured by another endorsement issued by us and made part of this Coverage Part.

(3) To any lessor of equipment:

(a) After the equipment lease expires; or

(b) If the "bodily injury", "property damage", "personal and advertising injury" arises out of sole negligence of the lessor

(4) To any:

(a) Owners or other interests from. whom land has been leased which takes place after the lease for the land expires; or

(b) Managers or lessors of premises if:

(i) The occurrence takes place after you cease to be a tenant in that premises; or

(ii) The "bodily injury", "property damage", "personal injury" or "advertising injury" arises out of structural alterations, new construction or demolition operations performed by or on behalf of the manager or lessor.

(5) To "bodily injury", "property damage" or "personal and advertising injury" arising out of the rendering of or the failure to render any professional services.

This exclusion applies even if the claims against any insured allege negligence or other wrongdoing in the supervision, hiring, employment, training or monitoring of others by that insured, if the "occurrence" which caused the "bodily injury" or "property damage" or the offense which caused the "personal and advertising injury" involved the rendering of or failure to render any professional services by or for you.

d. With respect to the insurance afforded to these additional insureds, the following is added to **SECTION III – LIMITS OF INSURANCE**:

The most we will pay on behalf of the additional insured for a covered claim is the lesser of the amount of insurance:

1. Required by the contract, agreement or permit described in Paragraph **a.**; or

2. Available under the applicable Limits of Insurance shown in the Declarations.

This endorsement shall not increase the applicable Limits of Insurance shown in the Declarations.

2. Additional Insured – Primary and Non-Contributory

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS,** Paragraph **4. Other insurance:**

Additional Insured – Primary and Non-Contributory

If you agree in a written contract, written agreement or permit that the insurance provided to any person or organization included as an Additional Insured under **SECTION II – WHO IS AN INSURED**, is primary and non-contributory, the following applies:

If other valid and collectible insurance is available to the Additional Insured for a loss covered under Coverages **A** or **B** of this Coverage Part, our obligations are limited as follows:

a. Primary Insurance

This insurance is primary to other insurance that is available to the Additional Insured which covers the

Additional Insured as a Named Insured. We will not seek contribution from any other insurance available to the Additional Insured except:

(1) For the sole negligence of the Additional Insured;

(2) When the Additional Insured is an Additional Insured under another primary liability policy; or

(3) when **b.** below applies.

If this insurance is primary, our obligations are not affected unless any of the other insurance is also primary. Then, we will share with all that other insurance by the method described in **c.** below.

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b. Excess Insurance

(1) This insurance is excess over any of the other insurance, whether primary, excess, contingent or on any other basis:

(a) That is Fire, Extended Coverage, Builder's Risk, Installation Risk or similar coverage for "your work";

(b) That is Fire insurance for premises rented to the Additional Insured or temporarily occupied by the Additional Insured with permission of the owner;

(c) That is insurance purchased by the Additional Insured to cover the Additional Insured's liability as a tenant for "property damage" to premises rented to the Additional Insured or temporarily occupied by the Additional with permission of the owner; or

(d) If the loss arises out of the maintenance or use of aircraft, "autos" or watercraft to the extent not subject to Exclusion **g.** of **SECTION I – COVERAGE A – BODILY INURY AND PROPERTY DAMAGE LIABILITY.**

(2) When this insurance is excess, we will have no duty under Coverages **A** or **B** to defend the insured against any "suit" if any other insurer has a duty to defend the insured against that "suit". If no other insurer defends, we will undertake to do so, but we will be entitled to the insured's rights against all those other insurers.

(3) When this insurance is excess over other Insurance, we will pay only our share of the amount of the loss, if any, that exceeds the sum of:

(a) The total amount that all such other insurance would pay for the loss in the absence of this insurance; and

(b) The total of all deductible and self insured amounts under all that other insurance.

We will share the remaining loss, if any, with any other insurance that is not described in this Excess Insurance provision and was not bought specifically to apply in excess of the Limits of Insurance shown in the Declarations of this Coverage Part.

c. Method Of Sharing

If all of the other insurance permits contribution by equal shares, we will follow this method also. Under this approach each insurer contributes equal amounts until it has paid its applicable limit of insurance or none of the loss remains, whichever comes first. If any of the other insurance does not permit contribution by equal shares, we will contribute by limits. Under this method, each insurer's share is based on the ratio of its applicable limit of insurance to the total applicable limits of insurance of all insurers

3. Blanket Waiver of Subrogation

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS,** Paragraph **8. Transfer Of Rights Of Recovery Against Others To Us**:

We waive any right of recovery we may have against any person or organization with whom you have a written contract that requires such waiver because of payments we make for damage under this coverage form. The damage must arise out of your activities under a written contract with that person or organization. This waiver applies only to the extent that subrogation is waived under a written contract executed prior to the "occurrence" or offense giving rise to such payments.

4. Bodily Injury Redefined

SECTION V – DEFINITIONS, Definition **3.** "bodily injury" is replaced by the following:

3. "Bodily injury" means bodily injury, sickness or disease sustained by a person including death resulting from any of these at any time. "Bodily injury" includes mental anguish or other mental injury resulting from "bodily injury".

5. Broad Form Property Damage – Borrowed Equipment, Customers Goods, Use of Elevators

a. SECTION I – COVERAGES, COVERAGE A – BODILIY INJURY AND PROPERTY DAMAGE LIABILITY, Paragraph **2. Exclusions** subparagraph **j.** is amended as follows:

Paragraph **(4)** does not apply to "property damage" to borrowed equipment while at a jobsite and not being used to perform operations.

Paragraphs **(3), (4)** and **(6)** do not apply to "property damage" to "customers goods" while on your premises nor do they apply to the use of elevators at premises you own, rent, lease or occupy.

b. The following is added to **SECTION V – DEFINTIONS:**

24. "Customers goods" means property of your customer on your premises for the purpose of being:

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a. worked on; or

b. used in your manufacturing process.

c. The insurance afforded under this provision is excess over any other valid and collectible property insurance (including deductible) available to the insured whether primary, excess, contingent

6. Knowledge of Occurrence

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS,** Paragraph **2. Duties in the Event of Occurrence, Offense, Claim or Suit:**

e. Notice of an "occurrence", offense, claim or "suit" will be considered knowledge of the insured if reported to an individual named insured, partner, executive officer or an "employee" designated by you to give us such a notice.

7. Liberalization Clause

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS:**

Liberalization Clause

If we adopt any revision that would broaden the coverage under this Coverage Form without additional premium, within 45 days prior to or during the policy period, the broadened coverage will immediately apply to this Coverage Part.

8. Medical Payments – Extended Reporting Period

a. **SECTION I – COVERAGES, COVERAGE C – MEDICAL PAYMENTS,** Paragraph **1. Insuring Agreement,** subparagraph **a.(3)(b)** is replaced by the following:

(b) The expenses are incurred and reported to us within three years of the date of the accident; and

b. This coverage does not apply if **COVERAGE C – MEDICAL PAYMENTS** is excluded either by the provisions of the Coverage Part or by endorsement.

9. Newly Acquired Or Formed Organizations

SECTION II – WHO IS AN INSURED, Paragraph **3.a.** is replaced by the following:

a. Coverage under this provision is afforded until the end of the policy period.

10. Non-Owned Watercraft

SECTION I – COVERAGES, COVERAGE A BODILY INJURY AND PROPERTY DAMAGE LIABILITY, Paragraph **2. Exclusions,** subparagraph **g.(2)** is replaced by the following:

g. Aircraft, Auto Or Watercraft

(2) A watercraft you do not own that is:

(a) Less than 51 feet long; and

(b) Not being used to carry persons or property for a charge;

This provision applies to any person who, with your consent, either uses or is responsible for the use of a watercraft.

11. Supplementary Payments Increased Limits

SECTION I – SUPPLEMENTARY PAYMENTS COVERAGES A AND B, Paragraphs **1.b.** and **1.d.** are replaced by the following:

1.b. Up to $2,500 for cost of bail bonds required because of accidents or traffic law violations arising out of the use of any vehicle to which the Bodily Injury Liability Coverage applies. We do not have to furnish these bonds.

1.d. All reasonable expenses incurred by the insured at our request to assist us in the investigation or defense of the claim or "suit", including actual loss of earnings up to $1000 a day because of time off from work.

12. Unintentional Failure to Disclose Hazards

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS,** Paragraph **6. Representations:**

We will not disclaim coverage under this Coverage Part if you fail to disclose all hazards existing as of the inception date of the policy provided such failure is not intentional.

13. Unintentional Failure to Notify

The following is added to **SECTION IV – COMMERCIAL GENERAL LIABILITY CONDITIONS,** Paragraph **2. Duties in the Event of Occurrence, Offense, Claim or Suit:**

Your rights afforded under this policy shall not be prejudiced if you fail to give us notice of an "occurrence", offense, claim or "suit", solely due to your reasonable and documented belief that the "bodily injury" or "property damage" is not covered under this policy.

ALL OTHER TERMS, CONDITIONS, AND EXCLUSIONS REMAIN UNCHANGED.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Sunrise Respiratory Care — MDEG License # (if applicable): _____

Physical Address: 6340 McLeod Rd #8

City: Las Vegas — State: NV — Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ — State: _____ — Zip: _____

Telephone: _____ — Website: www.sunriseresp.com

Licensing Company Email: csherman@sunriseresp.com

Section 2: Personal Information

First: Craig — Middle: ALLEN — Last: Sherman

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Carnegie ST [redacted]

City: Henderson — State: NV — Zip: 89052

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Beloit Memorial High School		6/80 - 6/82	
Address	**City**	**State**	**Zip**
1225 4th ST.	Beloit	WI	
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2015 - Present	[redacted] Carnegie ST [redacted]	Henderson	NV	89052
From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2015 - 02/20[redacted]	[redacted] chateau meada	Las vegas	NV	89129
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Sunrise Respiratory Care			From - To (MM/YY – MM/YY): 9/23 - Present
Business Address: 6340 Mallard Dr.	City: Las Vegas	State: NV	Zip: 89120
Phone: 949-398-6555	Title: OFFICE Manager		Number of Employed Hours: 80
Description of Duties: Oversee Facility			

Business Name: PulmoCare Respiratory			From - To (MM/YY – MM/YY): 9/13 - 9/23
Business Address: 2675 E Patrick Ln, #10 #	City: Las Vegas	State: NV	Zip: 89120
Phone: 702 419 5736	Title: OFFICE MANAGER		Number of Employed Hours: 20,800
Description of Duties: OFFICE MANAGMENT			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date 1/25/2024

I, Craig Sherman, **certify that as the MDEG Administrator for** Sunrise Respiratory Care,

that I (initial that you have read and meet the following requirements):

1. X Have a high school diploma or its equivalent;
2. X Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. X Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. X Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Craig Sherman
Print Name (First, Last)

Craig
Original Signature (electronic, copies or stamps not accepted)

10/30/2023
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sunrise Respiratory Care, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 6340 McLeod Rd #8

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Telephone: 9493986555 Website: www.sunriseresp.com

Licensing Company Email: management@sunriseresp.com

Section 2: Personal Information

First: Michael Middle: Last: Eilbert

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Noble Champions Way

City: Bartonville State: TX Zip: 76226

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Southern California School of Medicine		09/91-06/95	
Address	City	State	Zip
1975 Zonal Ave	Los Angeles	CA	90089
Diploma/Degree obtained, if any			
MD			

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		08/87 - 05/91	
Address	City	State	Zip
110 Sproul Hall #5800	Berkeley	CA	94720-5800
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Fountain Valley High School		09/83 - 06/87	
Address	City	State	Zip
17816 Bushard St	Fountain Valley	CA	92708
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/20 - present	[redacted]Noble Champions Way	Bartonville	TX	76226
From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/15 - 9/20	[redacted]Mahogany Run	Coto De Caza	CA	92694
From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/11 - 02/15	[redacted]rairestone Dr	Laguna Hills	CA	92653
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sunrise Respiratory Care			2010 - present	
Business Address		**City**	**State**	**Zip**
1881 Langley Ave		Irvine	CA	92614
Phone	**Title**			
949 945-3230	CFO			
Description of Duties				
Financial oversight and bookkeeping, insurance, accounting				

Business Name			From - To (MM/YY – MM/YY)	
Pacific Hospitalist Associates			1999- present	
Business Address		**City**	**State**	**Zip**
361 Hospital Rd #521		Newport Beach	CA	92663
Phone	**Title**			
	CFO / physician			
Description of Duties				
Shift based medical provider work within a hospital in Newport Beach California. Admisnistrative and financial Oversight				

Business Name			From - To (MM/YY – MM/YY)	
Michael J Eilbert MD Inc			06/08 - present	
Business Address		**City**	**State**	**Zip**
963 Noble Champions Way		Bartonville	TX	76226
Phone	**Title**			
949 945-3230				
Description of Duties				
Medical Legal consulting regarding medical-liability lawsuits and expert witness testimony				

Business Name			From - To (MM/YY – MM/YY)	
Hospital Road Insurance Company				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				
Captive Insurance program for Pacific Hospitalist Associates				

Business Name			From - To (MM/YY – MM/YY)	
MJE Texas Holdings LLC				
Business Address		**City**	**State**	**Zip**
963 Noble Champions Way		Bartonville	TX	76226
Phone	**Title**			
Description of Duties				
Real Estate Investment LLC				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Hebron Crossing Shops, LLC			
Business Address	**City**	**State**	**Zip**
963 Noble Champions Way	Bartonville	TX	76226
Phone	**Title**		
Description of Duties			
Real Estate Investment LLC			

Business Name			From - To (MM/YY – MM/YY)
Shoppes at Cascade			
Business Address	**City**	**State**	**Zip**
963 Noble Champions Way	Bartonville	TX	76226
Phone	**Title**		
Description of Duties			
Real Estate Investment LLC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	Orange County

Reason/Charge
Employment Practice Liability Claim

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Jennica Lindqvist	Lawsuit

Name of Business/Industry/Entity
Sunrise Respiratory Care

Provide explanation below:

Employee made claim of wrongful termination by employer. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

10/25/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	County of San Bernardino

Reason/Charge
Wage and Hour Payroll Claim

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Armando Flores	Lawsuit

Name of Business/Industry/Entity
Sunrise Respiratory Care

Provide explanation below:

Employee made wage and hour claim under California PAGA act. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

10/25/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
	2015	CA	Laguna Hills	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Arbitration Hearing		
Reason/Charge				
Real Estate Transactional Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Ades			Arbitration	
Name of Business/Industry/Entity				
Michael Eilbert				

Provide explanation below:

Residential Real Estate Transactional Dispute

Original Signature (electronic, copies or stamps not accepted)

10/25/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
	2013	CA		Los Angeles

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	LA county court

Reason/Charge
Small Claims Business Dispute

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Horizon Medical	Lawsuit

Name of Business/Industry/Entity
Sunrise Respiratory Care

Provide explanation below:

Small claims action. Uncontested. Debt paid.

Original Signature (electronic, copies or stamps not accepted)

10/25/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Eilbert

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/2/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, Michael Eilbert, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/2/2023

Date

Subscribed and Sworn to before me this 2nd day of November

Tyler C.

Notary Public Signature

TYLER COFFEE
Notary Public, State of Texas
Comm. Expires 06-26-2027
Notary ID 134425558

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Y

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Sunrise Respiratory Care, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1881 Langley Ave

City: Irvine State: CA Zip: 92614

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 9493986555 Website: www.sunriseresp.com

Licensing Company Email: management@sunriseresp.com

Section 2: Personal Information

First: Oscar Middle: Last: Munoz

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Stageline Dr

City: Laguna Hills State: CA Zip: 92653

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Long Beach Paramedical		9/1990 - 5/1992	
Address	**City**	**State**	**Zip**
3745 Long Beach Blvd	Long Beach	CA	90807
Diploma/Degree obtained, if any			
Respiratory Therapy			

School Name		From - To (MM/YY – MM/YY)	
Fountain Valley High School		9/1979 - 6/1983	
Address	**City**	**State**	**Zip**
	Fountain Valley	CA	92708
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2021	[redacted] Stageline Dr	Laguna Hills	CA	92653
2003 -2021	[redacted] Aurora Way	Mission Viejo	CA	92691
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sunrise Respiratory Care			2010 - present
Business Address	**City**	**State**	**Zip**
1881 Langley Ave	Irvine	CA	92614
Phone	**Title**		
949 290-6364	CEO, President, Director		
Description of Duties			
Overall operational management, supervision of respiratory services and sales force. Recruitment. Daily oversight.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Oscar Munoz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-8-24

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Oscar Munoz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-8-24

Date

Subscribed and Sworn to before me this 8th day of January, 2024.

Notary Public Signature

ANTONIO ARPON
Notary Public, State of Nevada
No. 14-13114-1
My Appt. Exp. March 12, 2026

(Seal)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Orange County		
Reason/Charge				
Employment Practice Liability Claim				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Jennica Lindqvist			Lawsuit	
Name of Business/Industry/Entity				
Sunrise Respiratory Care				

Provide explanation below:

Employee made claim of wrongful termination by employer. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	Orange County

Reason/Charge
Small Claims Business Dispute

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Horizon Medical	Lawsuit

Name of Business/Industry/Entity
Sunrise Respiratory Care

Provide explanation below:

Small claims action. Uncontested. Debt paid.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 8 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
	County of San Bernardino

Reason/Charge
Wage and Hour Payroll Claim

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Armando Flores	Lawsuit

Name of Business/Industry/Entity
Sunrise Respiratory Care

Provide explanation below:

Employee made wage and hour claim under California PAGA act. Settled without judgment.

Original Signature (electronic, copies or stamps not accepted)

7/13/23
Date

Nevada State Board of
Medical Examiners

Showing 7 result(s) for: **Munoz**

License Number	Last Name	First Name	Middle Name	Name Suffix	City	License Type	License Status	Specialties	
14522	ARCE-MUNOZ	Ivan			HENDERSON	Medical Doctor	Active	Family Medicine	View
LL3149	ESTRADA MUNOZ	Oscar	Ivan		Las Vegas	Resident	Expired	Surgery, General	View
20042	MUNOZ	Alex	F		Scottsdale	Medical Doctor	Active	Radiology, Diagnostic	View
RC1754	MUNOZ	Cindy	Angela		Las Vegas	Practitioner of Respiratory Care	Expired	Respiratory Care, General Floor Care, Pulmonary Rehab / Cardiac Rehab	View
416	MUNOZ	Nancy	Elizabeth		Watertown	Physician Assistant	Inactive	Physician Assistant, Family Practice	View
RC2136	MUNOZ-TELLO	Lissett			Las Vegas	Practitioner of Respiratory Care	Active	Respiratory Care	View
LL3799	Munoz	Maribel			Round Lake	Resident	Expired	Surgery, General	View

7 result(s)

Search again Download (.csv)

Nevada State Board of
Medical Examiners

Showing 0 result(s) for: **Eilbert**

License Number	Last Name	First Name	Middle Name	Name Suffix	City	License Type	License Status	Specialties

No matches found. Please search again with new criteria.

0 result(s)

Search again Download (.csv)

7

7A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-State	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Non-sterile Compounding
	☐ Location Change *	☐ Internet	☐ Sterile Compounding
	☐ Name Change*	☐ Nuclear	☐ Mail-Order Service
		☐ Other:	☐ Off-site Cognitive Services
	* If making a change, provide license #:		☐ Long Term Care
			☐ Hospital
	PH 04396		☒ Other: Letter of Protection

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☐ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☐ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☐ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Las Vegas Community Pharmacy

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-228-8498 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-228-8499 Contact Email: huntridge@mylvcp.com / adansolistorres@gmail.com

Website: https://www.lasvegascommunitypharmacy.com/

Nevada Business License # (if applicable) NV20212034388

Supervising/Managing Pharmacist Name (NRS 639.220): Natalie Nhu Nguyen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18735

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)	
Name: Julia Heshmati	NV Pharmacist Registration #: 09291
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.		

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)		
Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Rapid Rx, LLC

Mailing Address: 7488 W. Sahara Avenue

City: Las Vegas State: NV Zip: 89117

Telephone: 702-785-4966 Email: huntridge@mylvcp.com

Contact Person Name: Adan Solis Torres or Alexa Mirchou

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Anticipated New Chairman (title) for Las Vegas Communtiy Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Adan Solis Torres

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

09/11/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Adan Solis Torres hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Anticipated New Chairman (title) for Las Vegas Community Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 15 day of September, 2023

Notary Public

GABRIELA A SUAREZ
Notary Public, State of Nevada
Appointment No. 14-12698-1
My Appt. Expires Jan 21, 2026

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Natalie Nhu Nguyen Pharmacist Registration #: 18735

Pharmacy Name: Las Vegas Community Pharmacy

Initial each statement below to indicate you have read and agree with the following:

NN I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

NN I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

NN I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

NN I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

NN I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

09/14/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniela B Solis-Torres

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9.22.23

Date

Board Use Only	Date Received: 9/25/23	Amount: 500-CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Las Vegus Community Pharmacy, Inc**, as a DOMESTIC CORPORATION (78) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/05/2021, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/15/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202309153952024
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **Rapid Rx, LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/06/2023, and is in good standing in this state.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/15/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202309153952016
You may verify this certificate online at http://www.nvsos.gov

Section 12

List of all officers and directors

Company	Officer Names
Las Vegas Community Pharmacy	Adan Solis-Torres
Rapid Rx, LLC	Alexa Mirchou
	Daniela Solis-Torres

Top four stockholders and their percent ownership

Company	Percent	Name
Las Vegas Community Pharmacy	100	Rapid Rx, LLC
Rapid Rx, LLC	20	Alexa Mirchou
	20	Daniela Solis-Torres
	60	AAH Holdings, LLC
AAH Holding, LLC	50	Anna Heshmati
	50	Arlene Heshmati

All stockholders who hold 10% or more of the shares

Same as above: Top four stockholders and their percent ownership

Certificate of Corporate Status or Certificate of Good Standing

Attached hereto

Designated Representative Form

Attached Hereto

Personal History Record Application

Name	
Adan Solis-Torres	Attached hereto
Daniela Solis-Torres	Attached hereto
Alexa Mirchou	Attached hereto
Anna Heshmati	Attached hereto
Arlene Heshmati	Attached hereto

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LAS VEGAS COMMUNITY PHARMACY

Pharmacy/Wholesaler License # (if applicable) PH 04396

Physical Address 3200 N SOARING GULLS DR STE #101

City LAS VEGAS State NV Zip 89129

Mailing Address (if different from physical address) SAME AS ABOVE

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First NATALIE Middle NHU Last NGUYEN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] White Heron Court

City Las Vegas State NV Zip 89131

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
Roseman University of Health Sciences	09/09 - 06/13

Address	City	State	Zip
11 Sunset Way.	Henderson	NV	89014

Diploma/Degree obtained, if any: Doctor of Pharmacy

School Name	From - To (MM/YY – MM/YY)
College of Southern Nevada	09/05 - 05/08

Address	City	State	Zip
6375 W. Charleston Blvd.	Las Vegas	NV	89146

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/13 - Present	[redacted] White Heron Ct	Las Vegas	NV	89139
05/05 - 08/13	[redacted] Bella Lante Ave.	Las Vegas	NV	89141
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Wellness Pharmacy			From - To (MM/YY – MM/YY): 09/14 - 05/19	
Business Address: 50 N. Pecos Rd.	City: Henderson		State: NV	Zip: 89074
Phone: 702.912.1400	Title: Pharmacist. Part-time		Number of Employed Hours: 4,925	
Description of Duties: Received, filled, and dispensed medications. Processed third party claims and inventory control. Reviewed patient profiles. Counselling patients on medications				

Business Name: CVS Pharmacy			From - To (MM/YY – MM/YY): 03/11 - 12/12	
Business Address: 4595 E. Flamingo Rd	City: Las Vegas		State: NV	Zip: 89121
Phone: 702.436.9352	Title: Pharmacist Intern		Number of Employed Hours: 1,120	
Description of Duties: Received, filled, and dispensed medications. Counselled patients on medications. Transferred Rxs				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Natalie Nguyen, certify that as the designated representative for Las Vegas Community Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Natalie Nguyen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/31/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Natalie Nguyen
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/31/2023
Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss; County of CLARK

I, Natalie N. NGUYEN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/31/2023
Date

Subscribed and Sworn to before me this 31st day of August 2023

Notary Public Signature

SANDY RUBI MEJIA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 05-27-24
Certificate No: 20-3199-01

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Community Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 04396

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-228-8498 Website: www.lasvegascommunitypharmacy.com

Licensing Company Email: huntridge@mylvcp.com

Section 2: Personal Information

First: Alexa Middle: Last: Mirchou

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Mountain Lodge Dr.

City: Las Vegas State: NV Zip: 89144

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Loyola University Chicago			08/2021-08/2022	
Address		City	State	Zip
111 E Pearson St.		Chicago	IL	60611
Diploma/Degree obtained, if any				
Masters of Business Administration in Finance				
School Name			From - To (MM/YY – MM/YY)	
Loyola University Chicago			08/2017-05/2021	
Address		City	State	Zip
1032 W Sheridan Rd		Chicago	IL	60660
Diploma/Degree obtained, if any				
Bachelor Degree in Healthcare Administration				
School Name			From - To (MM/YY – MM/YY)	
The Meadows School			08/2013-05/2017	
Address		City	State	Zip
8601 Scholar Ln.		Las Vegas	NV	89128
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/22-09/23	[redacted] Mountain Lodge Dr.	Las Vegas	NV	89144
10/22-09/23	[redacted]V Couch Pl	Chicago	IL	60661
10/19-09/22	[redacted] Flower Spring St.	Las Vegas	NV	89134
05/21-09/22	[redacted]S La Salle St	Chicago	IL	60603
05/20-05/21	[redacted]W. Sheridan Rd.	Chicago	IL	60660
06/19-06/20	[redacted] W. Arthur Avenue	Chicago	IL	60626
08/18-12/18	[redacted] N Sheridan Road	Chicago	IL	60626
08/17-05/18	[redacted]N Kenmore Ave.	Chicago	IL	60660
01/99-10/19	[redacted]S. Valadez	Las Vegas	NV	89117
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Bellavue Medical, Bellavue Spine & Pain				From - To (MM/YY – MM/YY): 08/22-09/23
Business Address: 7488 W. Sahara Avenue	City: Las Vegas		State: NV	Zip: 89117
Phone: 702-641-1240	Title: Administrator / Shareholder			
Description of Duties: Front Desk Administrator for Medical Practice. Majority Shareholder for Bellavue Medical and Bellavue Spine & Pain.				

Business Name: Advocate Aurora				From - To (MM/YY – MM/YY): 05/21-/07/21
Business Address: 4440 W 95th Street	City: Chicago		State: IL	Zip: 60453
Phone: 708-684-8000	Title: Intern - REMOTE			
Description of Duties: Remote Intern for the public relations and marketing team for Advocate Aurora Hospital.				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alexa Mirchou

Print Name (First, Last)

Alexa Mir

Original Signature (electronic, copies or stamps not accepted)

09-20-23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of Clark

I, Alexa Mirchou, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Alexa Mir

Original Signature

09-20-23

Date

Subscribed and Sworn to before me this 20 day of Sept, 2023

Mary Anne Pham

Notary Public Signature

MARY ANNE PHAM
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-3210-01
MY APPT EXPIRES SEPTEMBER 16, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Community Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 04396

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-228-8498 Website: www.lasvegascommunitypharmacy.com

Licensing Company Email: huntridge@mylvcp.com

Section 2: Personal Information

First: Daniela Middle: Bertha Last: Solis-Torres

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Vegas Valley Dr

City: Las Vegas State: Nevada Zip: 89121

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pima Medical Institute - Las Vegas		2010-2012	
Address	**City**	**State**	**Zip**
3333 E Flamingo Rd	Las Vegas	NV	89121
Diploma/Degree obtained, if any			
Veterinary Assistant			

School Name		From - To (MM/YY – MM/YY)	
Sunrise Mountain High School		2010-2012	
Address	**City**	**State**	**Zip**
2575 Los Feliz St.	Las Vegas	NV	89156
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2020 - 09/2023	[redacted] Vegas Valley Dr	Las Vegas	NV	89121
10/2017 - 09/2020	[redacted] Ballard Dr	Las Vegas	NV	89104
06/2017 - 09/2017	[redacted] E Arizona Ave	Las Vegas	NV	89104
07/2002 - 05/2017	[redacted] Little Star Dr	Las Vegas	NV	89156
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Bellavue Medical			06/2023-09/2023
Business Address	**City**	**State**	**Zip**
7488 West Sahara Ave	LAs Vegas	NV	89117
Phone	**Title**		
(702)641-1240	Administrative Assistant		

Description of Duties

Greeted and welcomed clients upon arrival. Basic office duties such as answering emails, writing letters, faxing and scanning cases, and putting them where they need to go in the file management program. Answered and transferred phone calls to where they needed to go, and scheduled appointments for patients.

Business Name			From - To (MM/YY – MM/YY)
La Paloma Funeral Services			10/2019 - 07/2021
Business Address	**City**	**State**	**Zip**
5450 Stephanie St	Las Vegas	NV	89122
Phone	**Title**		
(702)732-7070	Office Coordinator		

Description of Duties

Managed & made in house prayer cards. Translated Mexican consulate paperwork. Processed CCSS paperwork, urns, and releases, along with preparing urns to be shipped out. Helped families manage projects for funeral services. Filed closed case files away / made sure that they were ready to be sent off and scanned. Managed closed case files.

Business Name			From - To (MM/YY – MM/YY)
The Billing Unit			12/2018 - 10/2019
Business Address	**City**	**State**	**Zip**
2700 E Sunset Rd	Las Vegas	NV	89120
Phone	**Title**		
(702)482-5823	Administrative Assistant		

Description of Duties

File and closed patient forms. Basic office duties such as sending letters, faxing and scanning cases.
Assist case managers with their patient files, and projects they work on.

Business Name			From - To (MM/YY – MM/YY)
CVBN Law Injury Lawyers			6/2017 - 10/2017
Business Address	**City**	**State**	**Zip**
9580 W Sahara Ave #180	Las Vegas	NV	89117
Phone	**Title**		
(702) 255-0700	Receptionist		

Description of Duties

Greeted and welcomed clients upon arrival. Basic office duties such as answering emails, writing letters, faxing and scanning cases, and putting them where they need to go in the file management program. Answered and transferred phone calls to where they needed to go. Helped draft motions to schedule and reduce traffic tickets

Business Name			From - To (MM/YY – MM/YY)
Green Valley Animal Hospital			2/2017-6/2017
Business Address	**City**	**State**	**Zip**
6150 S Mountain Vista S	Las Vegas	NV	89014
Phone	**Title**		
(702) 795-4440	Veterinary Assistant		

Description of Duties

Handled many high-pressure situations, such as surgeries and emergencies.
Dealt with clients, reassured and helped them.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
The Juice Bar at LVAC			10/2015 - 2/2017
Business Address	**City**	**State**	**Zip**
6560 Spencer St, Unit A-10 500	Las Vegas	NV	89119
Phone	**Title**		
(702)421-1329	Warehouse Supervisor/Receptionist		

Description of Duties

Maintained inventory
Basic office duties such as drafting and answering emails, writing letters, and making orders.

Business Name			From - To (MM/YY – MM/YY)
Mt Charleston Lodge & Cabins			11/2013 - 8/2014
Business Address	**City**	**State**	**Zip**
5375 Kyle Canyon Rd	Las Vegas	NV	89124
Phone	**Title**		
(702) 872-5408			

Description of Duties

Booked and calendared reservations of guests. Answered incoming phone calls. Checked guests in and out for their stay. Dealt with guests' complaints. Scheduled maintenance and housekeeping work.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniela Solis

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9.22.23

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Daniela Solis, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9.22.23

Date

Subscribed and Sworn to before me this 22 day of SEPTEMBER, 2023

Notary Public Signature

GREGORY PATER
Notary Public - State of Nevada
County of Clark
APPT. NO. 22-4196-01
My Appt. Expires: November 4, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Community Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 04396

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-228-8498 Website: www.lasvegascommunitypharmacy.com

Licensing Company Email: huntridge@mylvcp.com

Section 2: Personal Information

First: Anna Middle: Igorivna Last: Heshmati

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Royallon Drive

City: Las Vegas State: NV Zip: 89144

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Western Michigan University Cooley Las School			09/10 - 09/13
Address	**City**	**State**	**Zip**
300 S. Capitol Avenue	Lansing	MI	48933
Diploma/Degree obtained, if any			
J.D.			

School Name			From - To (MM/YY – MM/YY)
University of Nevada Las Vegas			08/07 - 05/10
Address	**City**	**State**	**Zip**
4505 S Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
BA			

School Name			From - To (MM/YY – MM/YY)
Palo Verde High School			
Address	**City**	**State**	**Zip**
333 S Pavilion Center D	Las Vegas	NV	89144
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/13 - 09/23	[redacted]Royalton Drive	Las Vegas	NV	89144
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AAH Holdings LLC			6/19-Current
Business Address	**City**	**State**	**Zip**
515 SOUTH 7TH STREET	Las Vegas	NV	89101
Phone	**Title**		
702-526-9852	Manager		
Description of Duties			
Manager			

Business Name			From - To (MM/YY – MM/YY)
Freelance Attorney			05/23-Current
Business Address	**City**	**State**	**Zip**
401 Royalton Drive	Las Vegas	NV	89144
Phone	**Title**		
(702) 526-9852	Attorney		
Description of Duties			
Freelance Attorney; Self-Employeed			

Business Name			From - To (MM/YY – MM/YY)
The Howard Hughes Corporation			01/19-05/23
Business Address	**City**	**State**	**Zip**
10485 Griffith Peak Drive, Suite 160	Las Vegas	NV	89135
Phone	**Title**		
702) 791-4000	In-House Legal / Attorney		
Description of Duties			
In-House Legal Services			

Business Name			From - To (MM/YY – MM/YY)
Noggle Law PLLC			07/15 - 12/18
Business Address	**City**	**State**	**Zip**
10161 Park Run Dr Ste 150	Las Vegas	NV	89145
Phone	**Title**		
	Case Manager / Law Clerk		
Description of Duties			
Legal Services			

Business Name			From - To (MM/YY – MM/YY)
ELENA PEDERSON, D.V.M., A PROFESSIONAL CORPORATION			01/20-Current
Business Address	**City**	**State**	**Zip**
8800 W. Charleston Blvd., Suite 6	Las Vegas	NV	89144
Phone	**Title**		
702-228-4711	Secretary		
Description of Duties			
Treasurer			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANNA Heshmati

Print Name (First, Last)

Ana Heshmati 9/22/23

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of NV, ss. County of Clark

I, ANNA Heshmati, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ana Heshmati 9/22/23

Original Signature Date

Subscribed and Sworn to before me this 22nd day of September 2023

Notary Public Signature

GABRIELA A SUAREZ
Notary Public, State of Nevada
Appointment No. 14-12698-1
My Appt. Expires Jan 21, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 -- Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Community Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 04396

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-228-8498 Website: www.lasvegascommunitypharmacy.com

Licensing Company Email: huntridge@mylvcp.com

Section 2: Personal Information

First: Adan Middle: n/a Last: Solis Torres

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]Vegas Valley Drive

City: Las Vegas State: NV Zip: 89121

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
William S. Boyd School of Law		8/2022-Present	
Address	**City**	**State**	**Zip**
4505 S. Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		1/2019-12-2021	
Address	**City**	**State**	**Zip**
4505 S. Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			
History, BA			

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		8/2014-12/2018	
Address	**City**	**State**	**Zip**
6375 W. Charleston Blvd	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
Paralegal Studies, AAS			

School Name		From - To (MM/YY – MM/YY)	
Valley High School		2010-2013	
Address	**City**	**State**	**Zip**
2839 Burnham Ave.	Las Vegas	NV	89169
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2020-Current	[redacted]Vegas Valley Drive	Las Vegas	NV	89121
10/2017-10/2020	[redacted]Ballard Dr	Las Vegas	NV	89104
5/2017-10/2017	[redacted]Arizona Ave	Las Vegas	NV	89104
8/2016-5/2014	[redacted]Ballard Dr	Las Vegas	NV	89104
8/2014-8/2016	[redacted]E. Atherton St	Long Beach	CA	90815
2010-8/2014	[redacted]Ballard Dr	Las Vegas	NV	89104
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Heshmati and Associates Law Offices	12/2018-Present

Business Address	City	State	Zip
515 S. 7th Street	Las Vegas	NV	89101

Phone	Title
702-432-1000	Case Manager/Law Clerk

Description of Duties: Legal Services

Business Name	From - To (MM/YY – MM/YY)
Benson Lee and Associates	3/2018-6/2018

Business Address	City	State	Zip
1820 E. Sahara Ave, Ste 110	Las Vegas	NV	89104

Phone	Title
702-477-7030	Paralegal

Description of Duties: Legal Services

Business Name	From - To (MM/YY – MM/YY)
Cogburn Law Offices	11/2017-3/2018

Business Address	City	State	Zip
2580 St. Rose Pkwy, Ste 330	Henderson	NV	89074

Phone	Title
702-857-6650	Paralegal

Description of Duties: Legal Services

Business Name	From - To (MM/YY – MM/YY)
CVBN Law	4/2017-11/2017

Business Address	City	State	Zip
9580 W. Sahara Ave, Ste 180	Las Vegas	NV	89117

Phone	Title
702-255-0700	Case Manager

Description of Duties: Legal Services

Business Name	From - To (MM/YY – MM/YY)
Lewis Law Firm	9/2016-4/2017

Business Address	City	State	Zip
709 Eastern Ave	Las Vegas	NV	89104

Phone	Title
N/A (went out of business)	Paralegal

Description of Duties: Legal Services

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Eiwin Mark Team at Wardley Real Estate			5/2018-10/2020
Business Address	**City**	**State**	**Zip**
777 N. Rainbow Blvd, Ste 120	Las Vegas	NV	89107
Phone	**Title**		
415-971-3379	Administrative Assistant		
Description of Duties			
Real Estate Administrative Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adan Solis Torres

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9-22-2023

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Adan Solis Torres, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9-22-2023

Date

Subscribed and Sworn to before me this 22 day of September.

Notary Public Signature

NOTARY PUBLIC
BRENDA DENNIS ESQUIVEL MORA
STATE OF NEVADA - COUNTY OF CLARK
MY APPOINTMENT EXP. OCT. 30, 2026
No: 22-4517-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Las Vegas Community Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH 04396

Physical Address: 3200 N. Soaring Gulls Dr. Ste 101

City: Las Vegas State: NV Zip: 89129

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 725-228-8498 Website: www.lasvegascommunitypharmacy.com

Licensing Company Email: huntridge@mylvcp.com

Section 2: Personal Information

First: Arlene Middle: Last: Heshmati

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] W. Quail Ave.

City: Las Vegas State: NV Zip: 89118

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
William S. Boyd School of Law			08/2004-05/2008	
Address		City	State	Zip
4505 S. Maryland Parkway		Las Vegas	NV	89154
Diploma/Degree obtained, if any				
Juris Doctor				
School Name			From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas			08/1999-05/2003	
Address		City	State	Zip
4505 S. Maryland Parkway		Las Vegas	NV	89154
Diploma/Degree obtained, if any				
Bachelor of Arts				
School Name			From - To (MM/YY – MM/YY)	
Basic High School			08/1995-06/1999	
Address		City	State	Zip
400 Palo Verde Dr.		Henderson	NV	89015
Diploma/Degree obtained, if any				
Honors High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2010- present	[redacted]W. Quail Ave.	Las Vegas	NV	89118
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Clark County Public Defender's Office			03/2012-present
Business Address	**City**	**State**	**Zip**
309 S. Third Street, #226	Las Vegas	NV	89155
Phone	**Title**		
702-455-3392	Chief Deputy Public Defender		
Description of Duties			
represent indigent defendants			

Business Name			From - To (MM/YY – MM/YY)
AAH Holdings LLC			06/2019 - present
Business Address	**City**	**State**	**Zip**
10655 Park Run Dr. Ste 130	Las Vegas	NV	89144
Phone	**Title**		
	Manager		
Description of Duties			
Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/22/2010	08/23/2010	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
10M22746X		Las Vegas Justice Court		
Reason/Charge				
battery				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Name of Business/Industry/Entity				

Provide explanation below:

Incident stemming from 01/22/2010 event which was resolved and closed.

Original Signature (electronic, copies or stamps not accepted)

09/21/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Arlene Heshmati

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/22/23

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Arlene Heshmati, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/22/23

Date

Subscribed and Sworn to before me this 22 day of September.

Notary Public Signature

NOTARY PUBLIC
BRENDA DENNIS ESQUIVEL MORA
STATE OF NEVADA - COUNTY OF CLARK
MY APPOINTMENT EXP. OCT. 30, 2026
No: 22-4517-01

(Seal)

7B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: Need to apply
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: NEVADA SPECIALTY PHARMACY

Physical Address: 556-E N. Eastern Ave

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: NEVADASPECIALTYPHARMACY@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) NV20232977765

Supervising/Managing Pharmacist Name (NRS 639.220): Waseem Sarwar

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20752

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Waseem Sarwar	NV Pharmacist Registration #: 20752
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): NA

Corporation/Organization Name: NEVADA SPECIALTY PHARMACY

Mailing Address: 556-E N. Eastern Ave

City: Las Vegas State: NV Zip: 89101

Telephone: _____ Email: NEVADASPECIALTYPHARMACY@GMAIL.COM

Contact Person Name: SALMAN AZEEM

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

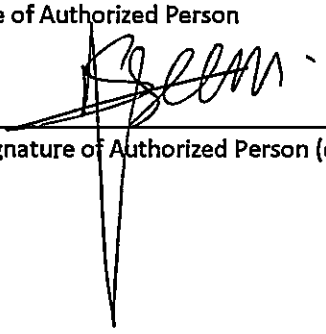
Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Nevada Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Salman Azeem

Print Name of Authorized Person



Original signature of Authorized Person (copies or stamps not accepted)

12/26/2023

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Salman Azeem hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Nevada Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26th day of December, 2023

Notary Public

CHARLES STICH
Notary Public, State of New York
Registration #01ST6268691
Qualified In Richmond County
Commission Expires 9/11/2024

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Waseem Sarwar Pharmacist Registration #: 20752

Pharmacy Name: Nevada Specialty Pharmacy

Initial each statement below to indicate you have read and agree with the following:

WS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

WS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

WS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

WS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

WS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/26/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Salman Azeem

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

12/26/2023

Date

Board Use Only	Date Received: 12/29/23	Amount: $500-cc

List all Officers and Directors

1. **SALMAN AZEEM** is the sole member of **NEVADA SPECIALTY PHARMACY** and he is the **President** of NEVADA SPECIALTY PHARMACY. He owns 100% shares of the corporation.

   i) **Contact information:**
   Salman Azeem

   Address: [redacted]
   South Richmond Hill,
   NY 11419

   Contact No: [redacted]
   Email: [redacted]

List the top four stockholders and their percent ownership

None

List all stockholders who hold 10% or more of the shares

None

Designated Representative

2. **WASEEM SARWAR** is the designated representative, who will be the supervising pharmacist of NEVADA SPECIALTY PHARMACY.

   i) **Contact Information:**
   Waseem Sarwar

   Address: [redacted]
   Las Vegas, NV 89119

   Contact No: [redacted]
   Email: [redacted]

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC CORPORATION (78) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Nevada Specialty Pharmacy** did, on 12/17/2023, file in this office the original Articles of Incorporation-For-Profit that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/17/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202312174199748
You may verify this certificate
online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Nevada Specialty Pharmacy

Nevada Business Identification # NV20232977765
Expiration Date: 12/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/17/2023.

Certificate Number: B202312174199749
You may verify this certificate online at http://www.nvsos.gov

FRANCISCO V. AGUILAR
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler NEVADA SPECIALTY PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 556-E N. EASTERN AVE

City Las Vegas State NV Zip 89101

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email nevadaspecialtypharmacy@gmail.com

Section 2: Personal Information

First WASEEM Middle _____ Last SARWAR

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Addre[redacted]S Nellis Blvd Ste 3

City Las Vegas State NV Zip 89121

Telephone [redacted] Email info.primecarerx@gmail.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF THE PUNJAB			01/2008-05/2013	
Address	**City**		**State**	**Zip**
ALLAMA IQBAL CAMPUS, MALL ROAD	LAHORE		PUNJAB	54000
Diploma/Degree obtained, if any				
PHARM D				
School Name			**From - To (MM/YY – MM/YY)**	
GOVT ISLAMIA COLLEGE			01/2005-12/2007	
Address	**City**		**State**	**Zip**
NEAR KACHEHRI,LOWER MALL ROAD	LAHORE		PUNJAB	54000
Diploma/Degree obtained, if any				
HIGHER SECONDARY SCHOOL CERTIFICATE				
School Name			**From - To (MM/YY – MM/YY)**	
DON BOSCO HIGH SCHOOL			01/1994 - 12/2005	
Address	**City**		**State**	**Zip**
NEAR POLICE LINES, EMPRESS ROAD	LAHORE		PUNJAB	54000
Diploma/Degree obtained, if any				
SECONDARY SCHOOL CERTIFICATE				
School Name			**From - To (MM/YY – MM/YY)**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address	**City**		**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/22-PRESENT	[redacted]E HARMON AVE APT 100	LAS VEGAS	NV	89119
From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/21-10/22	[redacted]OGALLALA STREET UNIT 1	PAHRUMP	NV	89048
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18-09/21	[redacted]116 STREET	SOUTH RICHMOND HILL	NY	11419
From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18-05/18	[redacted]LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/15-02/18	[redacted]EFFERTS BLVD	SOUTH OZONE PARK	NY	11420
From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/14-04/15	[redacted]7 STREET	WOOHHAVEN	NY	11421
From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/89-04/14	[redacted]A QAZAL BASH ROAD	LAHORE, PAKISTAN	PUNJAB	54000
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SAHARA PHARMACY			12/22 - PRESENT
Business Address	**City**	**State**	**Zip**
2585 S NELLIS BLVD STE 3	LAS VEGAS	NV	89121
Phone	**Title**		**Number of Employed Hours**
(702) 912-0800	PHARMACIST - OWNER / OPERATOR		40HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
PAHRUMP CARE PHARMACY			08/21 - PRESENT
Business Address	**City**	**State**	**Zip**
1500 E HIGHWAY 372, STE E	PAHRUMP	NV	89048
Phone	**Title**		**Number of Employed Hours**
(775) 727-3905	PHARMACIST - OWNER / OPERATOR		5 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
RITE AID PHARMACY			02/20 - 12/20
Business Address	**City**	**State**	**Zip**
840 WESTCHESTER AVE	BRONX	NY	10459
Phone	**Title**		**Number of Employed Hours**
(718) 378-4600	PHARMACIST MANAGER		38 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			01/18 - 02/20
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		**Number of Employed Hours**
(718) 641-4400	PHARMACIST		40 HOURS / WEEK
Description of Duties			
SUPERVISE DAILY OPERATIONS OF THE PHARMACY			

Business Name			From - To (MM/YY – MM/YY)
MEERAJ PHARMACY			
Business Address	**City**	**State**	**Zip**
115-17 LIBERTY AVENUE	SOUTH RICHMOND HILL	NY	11419
Phone	**Title**		**Number of Employed Hours**
(718) 641-4400	PHARMACY INTERN		40 HOURS / WEEK
Description of Duties			
WORK UNDER THE SUPERVISION OF PHARMACIST AND ASSIST THE PHARMACIST IN CARRYING OUT THE DAILY ACTIVITIES OF THE PHARMACY.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
MS BASHIR PHARMACY			07/13-06/15	
Business Address		**City**	**State**	**Zip**
SHOP NO 1& 2, STREET 13, WALTON ROAD		LAHORE	PUNJAB	54000
Phone	**Title**		**Number of Employed Hours**	
03214061992	PHARMACIST		40 HOURS / WEEK	
Description of Duties				
SUPERVISE DAILY OPERATIONS OF THE PHARMACY				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, WASEEM SARWAR, **certify that as the designated representative for**

NEVADA SPECIALTY PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WS I am at least 21 years of age;
3. WS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

WASEEM SARWAR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/26/2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WASEEM SARWAR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/26/2023

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Queens

I, WASEEM SARWAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/26/2023

Date

Subscribed and Sworn to before me this 26th day of DEC 2023

Notary Public Signature

CHARLES STICH
Notary Public, State of New York
Registration #01ST6268691
Qualified In Richmond County
Commission Expires 9/19/2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Nevada Specialty Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 556-E N. Eastern Ave,

City: Las Vegas State: NV Zip: 89101

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email: Nevadaspecialtypharmacy@gmail.com

Section 2: Personal Information

First: Salman Middle: Last: Azeem

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] 116 Street

City: South Richmond Hill State: NY Zip: 11419

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Universiti Sains Malaysia			09/16-09/17
Address	**City**	**State**	**Zip**
School of Pharmaceutical Sciences, Main Campus	Penang		11700
Diploma/Degree obtained, if any			
Masters in Clinical Pharmacy			

School Name			From - To (MM/YY – MM/YY)
University College Of Pharmacy, University of Punjab			09/06-09/11
Address	**City**	**State**	**Zip**
Allama Iqbal Campus, Mall Road	Lahore	Punjab	54000
Diploma/Degree obtained, if any			
Doctor Of Pharmacy			

School Name			From - To (MM/YY – MM/YY)
Government College University			09/04-09/06
Address	**City**	**State**	**Zip**
Government College University	Lahore	Punjab	54000
Diploma/Degree obtained, if any			
Higher Secondary School Certificate			

School Name			From - To (MM/YY – MM/YY)
Divisional Public School			01/94-01/04
Address	**City**	**State**	**Zip**
DPS School Rd, Township, Block 4 Sector A 2	Lahore	Punjab	54000
Diploma/Degree obtained, if any			
Secondary School Certificate			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20-Present	[redacted] 116 street	South Richmond Hill	NY	11419
10/17-03/20	[redacted] Street 7, NFC Society	Lahore, Pakistan	Punjab	54000
09/16-09/17	School of Pharmaceutical Sciences, USM	Penang, Malaysia		11700
03/14-08/16	King Abdul Aziz Rd, Military Area	Tabuk, Saudi Arabia		47512
01/07-02/14	[redacted] Street 7, NFC Society	Lahore, Pakistan	Punjab	54000

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
LIRX Pharmacy Inc. DBA Tomkin's Pharmacy and Health Care			07/23-Present
Business Address	**City**	**State**	**Zip**
930 Wheeler Road	Hauppauge	NY	11788
Phone	**Title**		
631-724-7096	President/Owner and Pharmacy Manager		
Description of Duties			
Supervise Daily Operations of the Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
LO NG Pharmacy Corp. DBA Victoria Pharmacy			03/23 -08/23
Business Address	**City**	**State**	**Zip**
4445 Kissena Blvd # A	Flushing	NY	11355
Phone	**Title**		
718-886-6200	Pharmacy Manager		
Description of Duties			
Supervise Daily Operations of the Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Lefferts Pharmacy Inc.			08/23-12/23
Business Address	**City**	**State**	**Zip**
117-06 Liberty Ave	Queens	NY	11419
Phone	**Title**		
718-880-2478	Supervising Pharmacist		
Description of Duties			
Supervising Pharmacist and supervise daily operations in the pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Dosepack Pharmacy LLC			01/23-07/23
Business Address	**City**	**State**	**Zip**
258-15 Hillside Ave. Store # 2	Queens	NY	11004
Phone	**Title**		
718-210-1477	Pharmacy Compliance Officer		
Description of Duties			
Supervise and conduct pharmacy's staff training (FWA, HIPPA)			

Business Name			From - To (MM/YY – MM/YY)
Clinical Pharmacy Inc. DBA CPW Pharmacy			01/22-01/23
Business Address	**City**	**State**	**Zip**
13107 Rockaway Blvd	South Ozone Park	NY	11420
Phone	**Title**		
718-322-5000	Pharmacy Intern		
Description of Duties			
Worked under the supervision of Pharmacist and assist the pharmacist in carrying out the daily activities of the Pharmacy			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Bay Pharmacy			11/21-02/22	
Business Address		**City**	**State**	**Zip**
2240 86th St		Brooklyn	NY	11214
Phone	**Title**			
718-73-2722	Pharmacy Tech			
Description of Duties				
Worked under the supervision of Pharmacist and assist the pharmacist in carrying out the daily activities of the Pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Shaukat Khanum Cancer Hospital and Research Centre			01/18-01/20	
Business Address		**City**	**State**	**Zip**
7 A Khayaban-e-Firdousi, Block R3 Block R 3 M.A Johar Town,		Lahore, Pakistan	Punjab	54000
Phone	**Title**			
+92 42 35905000	Staff Pharmacist			
Description of Duties				
Worked as Staff Pharmacist in outpatient, inpatient, chemo section and drug information center				

Business Name			From - To (MM/YY – MM/YY)	
King Salman Millitary Hospital			03/14-02/16	
Business Address		**City**	**State**	**Zip**
King Abdul Aziz Rd, Military Area		Tabuk, Saudi Arabia		47512
Phone	**Title**			
+966 14 441 1088	Staff Pharmacist			
Description of Duties				
Worked as Staff Pharmacist in outpatient, inpatient, chemo section and drug information center				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SALMAN AZEEM

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/26/2023

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Queens

I, Salman Azeem, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/26/23

Date

Subscribed and Sworn to before me this 26th day of DEC 2023

Notary Public Signature

CHARLES STICH
Notary Public, State of New York
Registration #01ST6268691
Qualified In Richmond County
Commission Expires 9/19/2024

(Seal)

7C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 03287	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FT5011363 ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☒ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Trinity Pharmacy

Physical Address: 2797 S maryland Pkwy #28

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 702-776-8210 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: trinity2810@yahoo.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Zorah Bernabe

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 15265

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Ma Lourdes J Jauregui	NV Pharmacist Registration #: 17035
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: Trinity Pharmacy LLC

Mailing Address: 2797 S Maryland Parkway, Unit 28

City: Las Vegas State: NV Zip: 89109

Telephone: [redacted] Email: [redacted]

Contact Person Name: Sanjay Veerkar

Please check type of partnership (NAC 639.214) ☑ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sanjay Veerkar hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for Trinity Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21 day of Nov, 20 23

Notary Public

JUSTICE ZH JOHN
Notary Public, State of Nevada
Appointment No. 22-2665-01
My Appt. Expires Mar 18, 2026

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Trinity Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Sanjay Veerkar

Print Name of Authorized Person

SVeerkar

Original signature of Authorized Person (copies or stamps not accepted)

11/07/2023

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Zorah Bernabe Pharmacist Registration #: 15265

Pharmacy Name: Trinity Pharmacy

Initial each statement below to indicate you have read and agree with the following:

ZB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

ZB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

ZB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

ZB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

ZB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Zorah Bernabe 11/07/2023

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sanjay Veerkar

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

11/07/2023

Date

Board Use Only	Date Received: 11/27/23	Amount: $500 - cc

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT5011363	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-23-2023

TRINITY PHARMACY LLC
TRINITY PHARMACY
2797 S. MARYLAND PKWY., STE 28
LAS VEGAS, NV 891098910

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FT5011363	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-23-2023

TRINITY PHARMACY LLC
TRINITY PHARMACY
2797 S. MARYLAND PKWY., STE 28
LAS VEGAS, NV 891098910

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada standing Revised Statutes which are either presently in a status of good standing or were in good for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence, **TRINITY PHARMACY LLC**, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/31/2014, and is in good standing in this state.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 11/10/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202311104106722
You may verify this certificate online at http://www.nvsos.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler TRINITY PHARMACY

Pharmacy/Wholesaler License # (if applicable) PH03287

Physical Address 2797 S MARYLAND PARKWAY STE 28

City LAS VEGAS State NV Zip 89109

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7027768210 Website _____

Licensing Company Email TRINITY2810@YAHOO.COM

Section 2: Personal Information

First ZORAH Middle COSUE Last BERNABE

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted] S MARYLAND PARKWAY STE 28

City LAS VEGAS State NV Zip 89109

Telephone [redacted] Email TRINITY2810@YAHOO.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
ROSALES NATIONAL HIGH SCHOOL			06/1980- 03/1984	
Address	City		State	Zip
PHILIPPINES				
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
SAINT LOUIS UNIVERSITY			06/1984 - 03/1988	
Address	City		State	Zip
PHILIPPINES				
Diploma/Degree obtained, if any				
BS PHARMACY				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/12 - 11/2023	[redacted]YOUNG SKY AVE	LAS VEGAS	NV	89142
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
TRINITY PHARMACY			10/2021 - CURRENT
Business Address	**City**	**State**	**Zip**
2797 S MARYLAND PARKWAY STE 28	LAS VEGAS	NV	89109
Phone	**Title**		**Number of Employed Hours**
7027768210	PHARMACY MANAGER		4500
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
WALGREENS PHARMACY 3844			04/2001 -09/2021
Business Address	**City**	**State**	**Zip**
5011 E SAHARA AVE	LAS VEGAS	NV	89142
Phone	**Title**		**Number of Employed Hours**
7025325633	STAFF PHARMACIST		38400
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, ZORAH COSUE BERNABE, **certify that as the designated representative for**

TRINITY PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZB I am at least 21 years of age;
3. ZB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

ZORAH BERNABE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-10-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ZORAH BERNABE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-10-2023

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Zohan Bernabe, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-10-23

Date

Subscribed and Sworn to before me this 10 day of Nov.

Notary Public Signature

(Seal)

JUSTICE ZH JOHN
Notary Public, State of Nevada
Appointment No. 22-2665-01
My Appt. Expires Mar 18, 2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Trinity Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2797 S Maryland Pkwy #28

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (702) 776-8210 Website: https://www.trinityrx.biz/

Licensing Company Email:

Section 2: Personal Information

First: Guru Middle: Last: Charan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] Caribbean Palm Drive

City: Las Vegas State: NV Zip: 89138

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Universit of Virginia - Darden School of Business		08/2005 - 05/2007	
Address	**City**	**State**	**Zip**
100 Darden Blvd,	Charlottesville	VA	22903
Diploma/Degree obtained, if any			
MBA - Finance			

School Name		From - To (MM/YY – MM/YY)	
Western Michigan University		01/1999 - 04/2001	
Address	**City**	**State**	**Zip**
1903 W Michigan Ave	Kalamazoo	MI	49008
Diploma/Degree obtained, if any			
M.S. - Computer Science			

School Name		From - To (MM/YY – MM/YY)	
Bangalore University		06/1994 - 05/1998	
Address	**City**	**State**	**Zip**
Mysore Rd, Jnana Bharathi	Bengaluru, India	KA	560056
Diploma/Degree obtained, if any			
B.Eng - Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

N/A

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2020 - Date	[redacted]aribbean Palm Dr	Las Vegas	NV	89138
06/2012 - 06/2020	[redacted]Valley Oaks Loop	Union City	CA	94587

N/A

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sagebrush Health			07/2020 - Date	
Business Address		**City**	**State**	**Zip**
8379 W Sunset Rd #210		Las Vegas	NV	89113
Phone	**Title**			
(702) 765-7246	Founder, CEO			
Description of Duties				
Own and operate 9 specialty medical clinics - Rheumatology, Neurology, Infectious Diseases				

Business Name			From - To (MM/YY – MM/YY)	
Wells Fargo Bank			06/2017 - 06/2020	
Business Address		**City**	**State**	**Zip**
420 Montgomery St		San Francisco	CA	94104
Phone	**Title**			
(866) 878-5865	Senior Vice President, Corporate Strategy			
Description of Duties				
Planning growth initiatives for bank products				

Business Name			From - To (MM/YY – MM/YY)	
H&R Block			11/2011 - 05/2017	
Business Address		**City**	**State**	**Zip**
1301 Main St		Kansas City	MO	64105
Phone	**Title**			
(805) 483-9601	Head of M&A, Strategy			
Description of Duties				
Planning organic and inorganic growth initiatives for tax filing products				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Guru Charan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/10/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark.

I, Guru Charan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/10/23

Date

State of Nevada County of Clark

Subscribed and Sworn to before me this 10th day of November by Guru Charan.

Laura L. Saenz

Notary Public Signature

LAURA L. SAENZ
Notary Public-State of Nevada
APPT. NO. 17-1445-1
My Appt. Expires 01-04-2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Trinity Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03287

Physical Address: 2797 S. Maryland Pkwy #28

City: Las Vegas State: NV Zip: 89109

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (702) 776 8210 Website: www.trinityrx.biz

Licensing Company Email: sanjay@axiohomes.com

Section 2: Personal Information

First: Sanjay Middle: Last: Veerkar

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]S Las Vegas Blvd, Unit 3501

City: Las Vegas State: NV Zip: 89109

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.179)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Univ of Chicago			08/09 - 05/13	
Address		City	State	Zip
450 Cityfront Plaza Dr		Chicago	IL	60611
Diploma/Degree obtained, if any				
MBA Finance				
School Name			From - To (MM/YY – MM/YY)	
Univ of Texas at Austin				
Address		City	State	Zip
2515 Speedway		Austin	TX	78712
Diploma/Degree obtained, if any				
Masters of Operations Research and Industrial Engineering				
School Name			From - To (MM/YY – MM/YY)	
MANIT				
Address		City	State	Zip
Link Road Number 3, Near Kali Mata Mandir		Bhopal, India		
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/18 - current	[redacted]S Las Vegas Blvd, Unit 3501	Las Vegas	NV	89109
From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/17 - current	[redacted] Mt Conness Way	Antioch	CA	94531
From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/15 - 06/17	[redacted]Creekwood Ct	Pittsburg	CA	94565
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Wells Fargo			05/15 - 11/23
Business Address	**City**	**State**	**Zip**
1755 Grant Street	Concord	CA	94520
Phone	**Title**		
800-869-3557	Risk Analyst		

Description of Duties
Risk Manager, detecting check fraud, working with other departments to identify fraud and implement procedures to reduce and control fraud.

Business Name			From - To (MM/YY – MM/YY)
TheMagicMist			01/14 - 04/15
Business Address	**City**	**State**	**Zip**
103 Schelter Rd, Suite 20	Lincolnshire	IL	60069
Phone	**Title**		
844-624-4264	Owner		

Description of Duties
Founder of company. Ecomerce marketing strategy, financial strategy.

Business Name			From - To (MM/YY – MM/YY)
eBay			01/13 - 01/14
Business Address	**City**	**State**	**Zip**
2025 Hamilton Ave	San Jose	CA	95125
Phone	**Title**		
866-643-1607	Marketing Manager		

Description of Duties
Analytics manager. Recommendations on marketing campaigns. Re-engineer customer and seller complaints process.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/20/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SANJAY VEERKAR

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/20/2023

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, SANJAY VEERKAR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/20/2023

Date

Subscribed and Sworn to before me this 20 day of NOV.

Notary Public Signature

JUSTICE ZH JOHN
Notary Public, State of Nevada
Appointment No. 22-2665-01
My Appt. Expires Mar 18, 2026

(Seal)

7D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Trusted Care Pharmacy

Physical Address: 1632 W Warm Springs RD

City: Henderson State: NV Zip: 89014

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-202-3900 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-202-2210 Contact Email: trustedcarepharm.info@gmail.com

Website: _____

Nevada Business License # (if applicable) NV20232930499

Supervising/Managing Pharmacist Name (NRS 639.220): Chisom Umeh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23243

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Chisom Umeh	NV Pharmacist Registration #: 23243
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NA

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: Chisom Umeh

Business Name: Trusted Care Pharmacy

Business Address: 1632 W Warm Springs RD

City: Henderson State: NV Zip: 89014

Telephone: 725-202-3900 Email: trustedcarepharm.info@gmail.com

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Trusted Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

CHISOM UMEH

Print Name of Authorized Person

Nwafoachisom

Original signature of Authorized Person (copies or stamps not accepted)

11/25/23

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: CHISOM UMEH Pharmacist Registration #: 23243

Pharmacy Name: Trusted Care Pharmacy

Initial each statement below to indicate you have read and agree with the following:

CU I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CU I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CU I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CU I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CU I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nwagbochisom
Original signature of Managing Pharmacist (copies or stamps not accepted)

11/25/23
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHISOM UMEH

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Nwagbochisom

Original signature of Authorized Person (copies or stamps not accepted)

11/25/23

Date

Board Use Only	Date Received: 11/29/23	Amount: $500 cc

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Trusted Care Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 1632 W Warm Springs RD

City: Henderson State: NV Zip: 89014

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: [redacted] Website:

Licensing Company Email: trustedcarepharm.info@gmail.com

Section 2: Personal Information

First: Chisom Middle: Last: Umeh

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: [redacted] Dunford ct

City: Henderson State: NV Zip: 89012

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences College of Pharmacy		08/19-05/22	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
Moreno Valley College		02/14-06/18	
Address	**City**	**State**	**Zip**
16130 Lasselle St	Moreno Valley	CA	92551
Diploma/Degree obtained, if any			
Associate Degree			
School Name		**From - To (MM/YY – MM/YY)**	
Riverside Adult School		01/14-12/14	
Address	**City**	**State**	**Zip**
6735 Magnolia Avenue	Riverside	CA	92506
Diploma/Degree obtained, if any			
G.E.D			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-11/23	[redacted]Dunford ct	henderson	NV	89012
08/22-07/23	[redacted]Mount Canyon street	Las Vegas	NV	89178
08/19-08/22	[redacted]W Warm Springs RD apt 3317	Hnderson	NV	89014
09/13-08/19	[redacted]Day street A301	Moreno Valley	CA	92553

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Sahara Pharmacy				
Business Address		**City**	**State**	**Zip**
2585 S Nellis Blvd		Las Vegas	NV	89121
Phone	**Title**			
7029120080	Pharmacist			
Description of Duties				
Staff-Phamarcist.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

NA

Nwagbochis Om

Original Signature (electronic, copies or stamps not accepted)

11/25/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHISOM, UMEH

Print Name (First, Last)

Nwagbochisom — 11/25/23

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Chisom Umeh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nwagbochisom — 11/25/23

Original Signature — **Date**

Subscribed and Sworn to before me this 25 day of November 2023

Jacel Avila

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
JACEL AVILA
My Appointment Expires
October 1, 2027
No. 23-5344-01

(Seal)

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, CHISOM UMEH hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Trusted Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Nwaghochisom
Signature

STATE OF NEVADA
COUNTY OF CLARK

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25th day of November, 2023

Notary Public

Notary Public - State of Nevada
COUNTY OF CLARK
JACEL AVILA
My Appointment Expires
October 1, 2027
No. 23-5344-01

SECRETARY OF STATE

NEVADA STATE BUSINESS LICENSE

TRUSTED CARE PHARMACY LLC

Nevada Business Identification # NV20232930499
Expiration Date: 10/31/2024

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 10/19/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202310194053043
You may verify this certificate online at http://www.nvsos.gov

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **TRUSTED CARE PHARMACY LLC** did, on 10/19/2023, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 10/19/2023.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202310194053042
You may verify this certificate online at http://www.nvsos.gov

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☑ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04518	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FI3299511 ☐ Non-sterile Compounding ☑ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Infused Therapies, LLC DBA Vital Care of Henderson

Physical Address: 9029 South Pecos Road Suite 2700

City: Henderson State: NV Zip: 89074

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725 205 4558 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725 735 6877 Contact Email: njcoulter@vitalcare.com

Website: https://vitalcare.com/locations/vital-care-of-henderson/referral/

Nevada Business License # (if applicable) 2023322842

Supervising/Managing Pharmacist Name (NRS 639.220): Nicholas Coulter

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Nicholas Coulter	NV Pharmacist Registration #: 23516
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Infused Therapies, LLC DBA Vital Care of Henderson

Mailing Address: 9029 S. Pecos Rd suite 2700

City: Henderson State: NV Zip: 89074

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for Infused Therapies, LLC DBA Vital Care of Henderson (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Sean Louvelle

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/6/2024

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sean louvelle hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for Infused Therapies, LLC DBA Vital Care of Henderson (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Sean Lou

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

Notary Public

See attachment Jurat

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Santa Clara

Subscribed and sworn to (or affirmed) before me on

this 06 day of 02, 2024, by
Date *Month* *Year*

(1) Sean Louvelle

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TIMMY DO
COMM # 2378232
Santa Clara County
California Notary Public
Comm Exp Oct. 12, 2025

Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information con deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2019 National Notary Association

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Nicholas Coulter Pharmacist Registration #: 23516

Pharmacy Name: Infused Therapies, LLC DBA Vital Care of Henderson

Initial each statement below to indicate you have read and agree with the following:

NC I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

NC I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

NC I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

NC I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

NC I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

2-6-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean louvelle

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Sean louvelle

Original signature of Authorized Person (copies or stamps not accepted)

2/6/2024

Date

Board Use Only	Date Received: 2/8/24	Amount: $500-00 ✓

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Vital Care of Henderson

NV Pharmacy or Outsourcing facility license # (if applicable): PH04518

Physical Address: 9029 South Pecos Road Suite 2700

City: Henderson State: NV Zip: 89012

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725 205 4558 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725 735 6877 Contact Email: njcoulter@vitalcare.com

Website: https://vitalcare.com/locations/vital-care-of-henderson/

Nevada Business License # (if applicable) 2023322842

Supervising/Managing Pharmacist Name (NRS 639.220): Nicholas Coulter

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23516

Name of Person with direct knowledge of compounding procedures: Nicholas Coulter

Email of Person with direct knowledge of compounding procedures: Nicholas Coulter

Telephone of Person with direct knowledge of compounding procedures: 435 256 1244

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

-Antiinfectives (Daptomycin, Ertapenem, Dalvance, Zosyn, Cefepime, etc)
-Antiinflammatories (Stelara, Entyvio, Tysabri, Orencia, etc)
-IVIG (Gammagard, Gammaked, Hizentra etc)

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
At the completion of compounding, before release and dispensing, the CSP must be visually inspected to determine whether the physical appearance of the CSP is as expected (e.g., it is inspected for evidence of inappropriate visible particulates or other foreign matter, discoloration, or other defects) using a black and then white background.
The inspection also must include a visual inspection of container – closure integrity

When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which could develop during storage.

8. How often do you perform glove fingertip and medial fill testing?
Upon starting with our pharmacy (prior to any compounding) and then every 6 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?
Personel will be retrained via competency modules and direct coaching/observation. A PDSA (plan/do/study/act) form will be filled out and overseen by the Performance Improvement Committee. The person will also be retested to assure a passing glove fingertip and/or media-fill test.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initially a didactic training program must be completed. This program comes directly from coporate Vital Care and includes interactive learning on areas such as gowing, garbing, cleaning, disinfection, aseptic technicque and information on general engineering controls and environments.
Upon completion of the didactic portion a candidate would then go through a hands-on competency checklist that would include all areas mentioned above. A candidate will also need to complete their own gloved fingertip test and media fill test.
All compounding personel are required to completed the above mentioned training annually.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

General cleaning practices: dirtiest to cleanest, unidirectional and overlapping wipes

Daily cleaning tasks completed with Preempt Plus in the ante and buffer rooms: pass through, floors, work surfaces
Monthly cleaning tasks completed with Peridox (sporicidal agent) in the ante and buffer rooms: pass through, floors, work surfaces, ceilings, walls, storage shelving and bins

Primary engineering control: interior is cleaned daily with sterile TB1-3300 follwed by 70% sterile IPA to remove residue and then monthly with sterile Peridox followed by 70% sterile IPA. Work surface within the hood is cleaned every 30 minutes with 70% sterile IPA

12. Who performs the sterile compounding process at your facility?
Nicholas Coulter

13. Who is responsible and accountable for the sterile compounding process at your facility?
Nicholas Coulter with direct support available from Vital Care corporate

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
We are using Kodiac Coolers. Their service provides packouts products and instructions. They perform summer and winter validations for their products to ensure temperatures are controlled in their products throughout the year.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)
1. List the specific high risk sterile products that your facility compounds:
2. What sterilization methods are utilized at your facility?
3. Does your facility utilize biological indicators? ☐ Yes ☐ No
4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicholas Coulter

Name of Person who Completed the Form

Pharmacist in Charge

Title

Signature (copies or stamps not accepted)

2-20-2024

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Infused Therapies, LLC DBA Vital Care of Henderson

Physical Address: 9029 S. Pecos Rd

City: Henderson State: NV Zip: 89074

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 408-981-8106 Website: N/A

Licensing Company Email: smlouvelle@vitalcare.com

Section 2: Personal Information

First: Sean Middle: Michael Last: louvelle

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] East San Fernando St. Unit 2011

City: San Jose State: Ca Zip: 95113

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty:

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials: SL

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
General Hospital School of Nursing		09/1992 - 07/1995	
Address	**City**	**State**	**Zip**
100 Forest Road	St. Johns, Nfld ,Canada	N/A	A1A 1E5
Diploma/Degree obtained, if any			
Registered Nurse			
School Name		**From - To (MM/YY – MM/YY)**	
Ascension Collegiate		09/89 - 06/91	
Address	**City**	**State**	**Zip**
Conception Bay Highway	Bay Roberts , Nfld, Canada	N/A	AOA- 3VO
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21 - Current	[redacted] East San Fernando St. Unit 2011	San Jose	Ca	95113
08/20- 03/21	[redacted] Palomares Rd.	Castro Valley	Ca	94522
06/04- 08/20	[redacted] Corte De Belleza	San Jose	Ca	95120
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Good Samaritan Hospital		06/1997- Current	
Business Address	**City**	**State**	**Zip**
2425 Samaritan Drive	San Jose	Ca	95124
Phone	**Title**		
(408) 559-2462	Registered Nurse		

Description of Duties

Currently working in a surgical clinic (PAT) obtaining patients history and preparing them for surgery.

Business Name		From - To (MM/YY – MM/YY)	
Sean Louvelle (Sole proprietorship)		06/2021 - 04/01/23	
Business Address	**City**	**State**	**Zip**
N/A	San Jose	Ca	95113
Phone	**Title**		
(408) 981-8106	Infusion Nurse		

Description of Duties

Doing home infusions for patients . Monitoring for signs and symptoms of adverse drug reactions/patient assessments.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sean Louvelle

Print Name (First, Last)

Sean Louvelle — 2/6/2024

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Santa Clara

I, Sean Louvelle, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sean Louvelle — 2/6/2024

Original Signature — **Date**

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See attachment Jurat

(Seal)

Applicant's initials SL

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Santa Clara

Subscribed and sworn to (or affirmed) before me on

this 06 day of 02, 2024, by
Date *Month* *Year*

(1) Sean Louvelle

(and (2) _____),
Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

TIMMY DO
COMM # 2378232
Santa Clara County
California Notary Public
Comm Exp Oct. 12, 2025

Signature _____
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Infused Therapies, LLC DBA Vital Care of Henderson

Physical Address 9029 S. Pecos Rd

City Henderson State NV Zip 89074

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 725 205 4558 Website https://vitalcare.com/locations/vital-care-of-henderson/referral/

Licensing Company Email _____

Section 2: Personal Information

First Nicholas Middle Jacob Last Coulter

Alias(es, nicknames, name changes, etc.) Nick

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted] Smoketree Village Circle

City Henderson State NV Zip 89012

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Applicant's initials NC

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University		06/15-06/18	
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Utah Tech University		08/07-05/15	
Address	**City**	**State**	**Zip**
225 S. Univeristy Ave	Saint George	UT	84770
Diploma/Degree obtained, if any			
Bachelor's of Science			

School Name		From - To (MM/YY – MM/YY)	
Pine View High School		08/03-08/08	
Address	**City**	**State**	**Zip**
2850 East 750 North	Saint George	UT	84790
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/24-present	[redacted] Smoketree Village Circle	Henderson	NV	89012
05/23-01/24	[redacted] Blackrodge Road	Henderson	NV	89015
04/21-05/23	[redacted] Woodlake Blvd	Stow	OH	44224
06/19-03/21	[redacted] Robin Lane	Stow	OH	44224
06/18-06/19	[redacted] Wyndham Ridge Dr. #102	Stow	OH	44224
05/17-06/18	[redacted] Amherst Dr. # 2001	Sagamore Hills	OH	44067
05/15-05/17	[redacted] Paradise Coach Drive	Henderson	NV	89002
05/13-05/15	[redacted] W. 100 S. #3	Saint George	UT	84770
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Vital Care of Henderson			06/23-Present	
Business Address		**City**	**State**	**Zip**
9029 S. Pecos Rd Suite 2700		Henderson	NV	89074
Phone	**Title**		**Number of Employed Hours**	
725 205 4558	Pharmacist in Charge		960	

Description of Duties

Preparing new pharmacy for accredidation including creating job aids, policies and educational material. Managing logs for cleanroom and pharmacy. Coordinating cleanroom maintenance and general upkeep

Business Name			From - To (MM/YY – MM/YY)	
Cleveland Clinic Akron General			07/19-06/23	
Business Address		**City**	**State**	**Zip**
1 Akron General Ave		Akron	OH	44307
Phone	**Title**		**Number of Employed Hours**	
330 344 6000	Clinical Pharmacist		7,500	

Description of Duties

Oversaw technician compounding, cleanroom maintenance and drug purchasing. Verfied physician orders and followed up with them when problems were detected. Counseled patients on their IV therapies including chemotherapy..

Business Name			From - To (MM/YY – MM/YY)	
Cleveland Clinic South Pointe			07/18-07/19	
Business Address		**City**	**State**	**Zip**
20000 Harvard Ave		Warrensville Heights	OH	44122
Phone	**Title**		**Number of Employed Hours**	
216 491 6000	Pharmacy Resident		2,080	

Description of Duties

Rounded on patients, verified physician orders, counseled patients, oversaw general pharmacy operations including sterile compounding

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Nicholas Coulter, **certify that as the designated representative for**

Infused Therapies LLC, DBA Vital Care of Henderson,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Nicholas Coulter

Print Name (~~First~~, Last)

Original Signature (electronic, copies or stamps not accepted)

2-6-2024

Date

Applicant's initials NC

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicholas Coulter
Print Name (First, ~~Last~~)

Original Signature (electronic, copies or stamps not accepted)

2-6-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Nicholas Coulter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-7-2024
Date

Subscribed and Sworn to before me this 07 day of February 2024.

Notary Public Signature

SUE ANN TREZZA
Notary Public, State of Nevada
Appointment No. 22-5381-01
My Appt. Expires Jul 13, 2026

(Seal)

Applicant's initials NC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Infused Therapies LLC DBA Vitalcare

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 9029 South Pecos suite 2900

City: Henderson State: NV Zip: 89074

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Alberto Middle: Last: fernandez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted] San Ramon Valley Blvd suite 370

City: Danville State: Ca Zip: 94526

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Plantation High School		1978-1982	
Address	**City**	**State**	**Zip**
6901 NW 16 th street	Plantation	FL	33313
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2021 to Present	[redacted] North Sheridan Road	Lakeforest	IL	60045
2018 to 2021	[redacted] Hillside Road	Danville	CA	94526
2003 to 2018	[redacted] Palomares Road	Castro Valley	CA	94562

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
TSE			2015 to present
Business Address	**City**	**State**	**Zip**
1900 Powell Street suite 700	Emeryville	CA	95608
Phone	**Title**		
415 913 8274	Chairman		

Description of Duties
Stared and own 50% of the company and have 100% control. TSE employs approximately 50 people and consults in the Transit Industry to public agency's in North America.

Business Name			From - To (MM/YY – MM/YY)
B&C Transit, Inc			1997 to 2021
Business Address	**City**	**State**	**Zip**
1924 FRANKLIN STREET	OAKLAND	CA	94612
Phone	**Title**		
51048335660	CEO - OWNER		

Description of Duties
Construction and Enginerring company performing work across the USA in RAil Transit. Was responsible for all aspects of buisness. Employed 110-120 people. Owned 90% of company and sold company to Alstom Signalling in 2021.

Business Name			From - To (MM/YY – MM/YY)
Edgewater Properties LLC			2011 to Present
Business Address	**City**	**State**	**Zip**
696 San Ramon Valley Blvd	Danville	CA	94526
Phone	**Title**		
3233275588	CEO		

Description of Duties
Own 100% of company, manage and own varies real estate holding across the country.

Business Name			From - To (MM/YY – MM/YY)
Star City Hockey LLC			
Business Address	**City**	**State**	**Zip**
1880 Transformation Drive	Lincoln	NE	68501
Phone	**Title**		
1402474 7823	Managing Member		

Description of Duties
Own 99% of company. Company operates the Lincoln Stars hockey team and the facility called the Ice Box in Lincoln Nebraska. The Ice Box sits on the University of Nebraska campus and has a capcity of 4500 people. Company employ 15-20 fulltime employes and some 50 part time employees.

Business Name			From - To (MM/YY – MM/YY)
Tri Valley Ice LLC			2012 to Present
Business Address	**City**	**State**	**Zip**
6601 Preston Road Unit D	Livermore	CA	
Phone	**Title**		
19256066900	CEO		

Description of Duties
Own 95%. Company operates the ice rinks at Livermore and Dublin. These are privately held facilities that provide ice sports to the community. Employs 10 full time employees and several part time employees.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
F&S Management LLC			2018-Presnt
Business Address	**City**	**State**	**Zip**
99 Almaden Blvd suite 333	San Jose	CA	95113
Phone	**Title**		
5503020770	Managing Member		
Description of Duties			
Own 75%. Company owns and operates the North Iowa Bulls and the Mason City Toros Junior Hockey team which play out of Mason City Iowa.			

Business Name			From - To (MM/YY – MM/YY)
Infused Theraples LLC			2022 to Present
Business Address	**City**	**State**	**Zip**
9029 South Pecos	Henderson	NV	
Phone	**Title**		
	Managing Member		
Description of Duties			
Own 60% Company formed to purchase a vitalcare franchise. Other than financial management will not participate in the day to day operations.			

Business Name			From - To (MM/YY – MM/YY)
General Railway Signal-GRS			1993 to 1997
Business Address	**City**	**State**	**Zip**
	Rochester	NY	
Phone	**Title**		
	Resident Engineer		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
US&S			1984-1993
Business Address	**City**	**State**	**Zip**
	Pittsburgh	PA	
Phone	**Title**		
	Signaling Field Tech to Signal Field Engineer for Rail Transit		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
See below	See below	See below	See below	See below
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
See below		See below		
Reason/Charge				
See below				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
See below			See below	
Name of Business/Industry/Entity				
See below				

Provide explanation below:

1. B&C Transit v. Regional Connector Constructors, et al,
Los Angeles Superior Court, Case No. 19STCV14212
Filed 4/24/2019, Dismissed 3/26/2020.
Primary Issue: Non Payment
2. CON J FRANKE ELECTRIC VS. WEST BAY BUILDERS
Contra Costa Superior Court, Case Number MSC15-00537
Filed 3/25/2015, Dismissed: 1/31/2017
Primary Issue: Claim for work performed
3. B & C Transit Consultants Inc vs. San Diego Association of Governments
San Diego Superior Court, Case No. 37-2009-00096863-CU-WM-CTL
Filed 08/25/2009, Dismissed: 9/22/2009
Primary Issue: Claim that specs were discriminatory.
4. B & C Transit, Inc. vs. Elcon Corporation
US District Court District of Oregon – Portland Division, Case No. CV11-1534-AA
Filed 12/11/11, Dismissed: 6/26/2013
Primary Issue: Breach of Contract
5. Joseph Grintsaig vs. B&C Transit, Inc.
Superior Court of California – Alameda County
Filed 2/10/2012, Settled 10/27/2012
Primary Issue: Breach of Oral Contract
6. Cornfield Consulting LLC vs. Alberto Fernandez, et al
District Court – 73rd Judicial District, Bexar County, TX
Filed 1/18/2022, Dismissed 7/25/22
Primary Issue: Oral Contract Dispute
7. Erin Dale Bridges and Carmela Bridges, v. Blocka Construction, Inc., B&C Transit, Inc.
Superior Court of the State of California County of Contra Costa Case Number: C18-00452
Primary Issue: Job Injury referred to Workers' Comp - June 2021

Original Signature (electronic, copies or stamps not accepted)

2-13-2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ALBERTO FERNANDEZ

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2-13-2024

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of CONTRA COSTA

I, ALBERTO FERNANDEZ, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2-13-2024

Date

Subscribed and Sworn to before me this 13 day of February, 2024

Notary Public Signature

BEN WEINER
Notary Public - California
Contra Costa County
Commission # 2352785
My Comm. Expires Apr 14, 2025

(Seal)

vitalcare
INFUSION SERVICES
of Henderson

Subject: Authorization for Nicholas Coulter to Speak on Behalf of Vital Care of Henderson

Dear Member of the Nevada State Board of Pharmacy,

I hope this letter finds you well. I am writing to request authorization for Mr. Nicholas Coulter, the pharmacist in charge of Vital Care of Henderson, to speak on behalf of our pharmacy during any official proceeding or communications with the Nevada Board of Pharmacy.

I believe that Nicholas Coulter possesses the necessary expertise, knowledge of the Nevada Board of Pharmacy's rules and regulations, and experience to effectively represent Vital Care Pharmacy during discussions or inquiries with Nevada Board of Pharmacy.

Sincerely,

Alberto Fernandez

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/2S/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Closed door, long-term care pharmacy	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☒ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Med-Plus Pharmacy

Physical Address: 335 Lindbergh Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 888-222-8405 Toll Free # (NAC 639.708, NRS 639.23286): 888-222-8405

Fax: 866-530-2069 Contact Email: ghunt@polarisrx.com

Website: www.polarisrx.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Neil Farage

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09369

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____
Name: _____	NV Pharmacist Registration #: _____

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____
Name: _____	Credentials: _____	%: _____

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Polaris Pharmacy Services, LLC

Corporation/Organization Name: Med-Plus Pharmacy, Inc.

Mailing Address: 2900 NW 60th St.

City: Fort Lauderdale State: FL Zip: 33309

Telephone: 800-589-9747 Email: ghunt@polarisrx.com

Contact Person Name: Gina Hunt

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Med-Plus Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David Rombro

Print Name of Authorized Person

CEO

Original signature of Authorized Person (copies or stamps not accepted)

12/1/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Rombro

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

CEO

Original signature of Authorized Person (copies or stamps not accepted)

12/1/23

Date

Board Use Only	Date Received: 12/5/23	Amount: $500-check 1319

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	MED-PLUS PHARMACY, INC.
Entity No.:	2480380
Registration Date:	08/09/2002
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of July 18, 2023.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 130660622

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

December 12, 2023

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name: MED-PLUS PHARMACY

License Type: PHARMACY

License Number: PHY 58705

Status: ACTIVE

Issue Date: 08/31/2022

Expiration Date: 08/01/2024

Address of Record: 335 LINDBERGH AVE LIVERMORE, CA 94551

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Anne Sodergren
Executive Officer

By

Ann Altamirano
Public Inquiry Analyst
(916) 518-3045
Pharmacy.PublicRecords@dca.ca.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Med-Plus Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 335 Lindbergh Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 888-222-8405 Toll Free # (NAC 639.708, NRS 639.23286): 888-222-8405

Fax: 866-530-2069 Contact Email: ghunt@polarisrx.com

Website: www.polarisrx.com

Nevada Business License # (if applicable) Pending

Supervising/Managing Pharmacist Name (NRS 639.220): Neil Farage

Supervising/Managing Pharmacist NV Pharmacist Registration #: 09369

Name of Person with direct knowledge of compounding procedures: Younhi Woo

Email of Person with direct knowledge of compounding procedures: ywoo@polarisrx.com

Telephone of Person with direct knowledge of compounding procedures: 888-222-8405x3999

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Prospective Drugs,

IV antibiotics sych as Aminoglicosides (Tobramycin, Amikacin, gentamicin), amphotericins b, Daptomycin, and all non-standard strengths of vancomycin, ceftriaxone, cefazolin, Cefepime, Cefoxitin, Ceftazidime, Ertapenem, and Primaxin

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
N/A

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?

All final products will be tested visually using LED light inspection boxes for particulate matter and turbidity.

8. How often do you perform glove fingertip and medial fill testing?
Every 6 months according to the guidelines of USP-797 for all designated compounding personnel

9. What is your policy if an employee fails a glove fingertip or media-fill test?
If any portion of the the tests does not meet the minimum passing result, the respective Competency is repeated in its entirety. Failures in other Core Competencies are repeated individually. Documentation of the failure, corrective actions, and the repeated competency results is retained and readily accessible. In the event of 1st failure, retraining and coaching first then repeat the test, on 2nd failure, extensitive knowledge and skill retaining and repeat the test, with 3rd failure, we reassign the employee to non-compounding duty and consider referral to HR.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial Gloved Fingertip and Thumb Sampling Assessment (GFS): successfully completed three separate times prior to compounding independently; each GFS is conducted separately after a completing the hand hygiene and garbing procedure
Ongoing Gloved Fingertip and Thumb Sampling Assessments: successfully completed at least once every 6 (six) months for Compounding Personnel requalification
After initial knowledge training, we 'observe', 'validate', then perform 3 separate assessment with 6 plates and 7 days incubation targeting 0 CFU.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
The cleaning protocol ins composed of three general procedure done by daily, weekly, and monthely.
A. Daily cleaning procedure includes
(1) Hood cleaning using Contec and sIPA to remove any residues, and (2) Everything else- (ISO 7 & 80 including but not limited to:carts, pass through, high-touch surfaces (phone, door handle, etc) sink surface,
B. Weekly cleaning procedure is
Using the same procedure with daily cleaning, we clean the exterior of hood (top, side and back) then clean exterior and interior of sink and leg)
C. Monthly
we clean Hood (w/sterile peridox and sIPA), Ceiling/Anteroom wall (using Peridox and sIPA), Glass walls (using peridox, sIPa) and Saticide) then all other surfaces and refrigerator with 70% IPA
(see the attached)

12. Who performs the sterile compounding process at your facility?

All pharmacists and IV technicians who are trained as aforementioned

13. Who is responsible and accountable for the sterile compounding process at your facility?
Lead IV pharmacist (Trish Ho)

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

The final products are delivered within the same day in a temper-resistant plastic bag and/or temperature-controlled packaging (in either styrofoam boxes or insulated packages with ice bricks to the destinations). The quantity of ice brick is determined by established cold-chain studies.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)
1. List the specific high risk sterile products that your facility compounds:
2. What sterilization methods are utilized at your facility?
3. Does your facility utilize biological indicators? ☐ Yes ☐ No
4. If yes, describe how they are utilized:

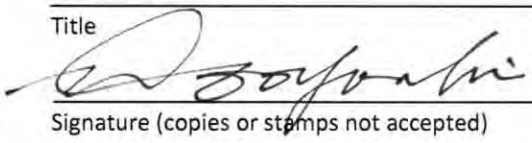
I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Younhi Woo

Name of Person who Completed the Form

Pharmacist-In-Charge

Title



Signature (copies or stamps not accepted)

11/28/2023

Date

Board Use Only	Date Received: 12/5/23 Date Approved: _____ Approved By: _____

Polaris Pharmacy Services

STERILE COMPOUNDING/ANTE AREA QUALITY ASSURANCE ENVIRONMENTAL CLEANING MAINTENANCE LOG

IV HOOD CERTIFICATION DUE DATE:	MONTH:
	YEAR:

DAILY TASKS	CLEAN ROOM (WITH CLEANING AGENT)	ANTE-ROOM
	1. CLEAN INSIDE HOOD **CEILING * DIFFUSER * INSIDE HOOD WALLS (BACK TO FRONT) *REMOVE BAR THEN CLEAN BAR & HOOKS, REASSEMBLE* CLEAN HOOD COUNTER TOP & EDGE.* 2. CLEAN TRANSFER CART, (TOP TO BOTTOM) & CLEAN EMPTY BINS FOR IV ORDERS . 3. CLEAN HAND ANTISEPTIC DISPENSER 4.CLEAN PASSING THROUGH WINDOW OUTSIDE THEN INSIDE; TOP TO BOTTOM 5. EMPTY WASTE & WIPE WASTE HOLDER, REPLACE LINERS. 6. MOP CLEAN ROOM FLOOR **START WITH THE CORNERS FURTHEST AWAY FROM ENTRY DOORS TO MINIMIZE CROSS CONTAMINATION.* 7. CLEAN DOOR HANDLE	1. CLEAN TRANSFER CART 2. CLEAN HAND ANTISEPTIC DISPENSER 3.EMPTY WASTE & WIPE WASTE HOLDER, REPLACE LINERS . 4. CLEAN SINK AND FAUCET *(TOP TO BOTTOM)* 5. MOP ANTEROOM FLOOR **START WITH THE CORNERS FURTHEST AWAY FROM ENTRY DOORS TO MINIMIZE CROSS CONTAMINATION.* *6.CLEAN DOOR HANDLE*

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
TECH INITIAL																															
SOLUTIONS USED (TBI/PM)																															
Start Time solution applied																															
End Time solution removed																															

CLEANROOM & ANTEROOM: 1. CLEAN EXTERIOR OF HOOD **START TOP, SIDES & BACK. 2. CLEAN SUPPLY SHELF/BINS(eg: FOR NEEDLES, SYRINGES, IVPB)* 3. CLEAN EXTERIOR OF SINK & LEG

WEEKLY TASKS	WEEK 1	WEEK 2	WEEK 3	WEEK 4
TECH INITIAL/DATE/TIME				
SOLUTIONS USED (TBI/PM/PD)				
Start Time solution applied				
End Time solution removed				

MONTHLY TASKS	CLEAN ROOM: 1. CLEAN CEILING 1ST THOROUGHLY WITH APPROPRIATE DISINFECTANT, THEN CLEAN THE WALLS (FROM TOP TO BOTTOM SYSTEMATICALLY FROM THE FAR SIDE TOWARD THE NEXT WALL, CLEAN WALL DIRECTLY BEHIND HOOD, CLEAN WINDOW AND DOOR (TOP TO BOTTOM). 2. CHECK/CLEAN PRE-FILTER COVER (TOP TO BOTTOM).	ANTE-ROOM: 1. CLEAN CEILING 1ST THOROUGHLY WITH APPROPRIATE DISINFECTANT, THEN CLEAN THE WALLS (FROM TOP TO BOTTOM SYSTEMATICALLY FROM THE FAR SIDE TOWARD THE NEXT WALL, CLEAN WINDOW AND DOOR (TOP TO BOTTOM).	**Refrigerator (R)** **Incubator (I):** clean thoroughly with appropriate cleanser. Passing window outside(W)
TECH INITIAL/DATE/TIME			R ☐ I ☐ W
SOLUTIONS USED (PD)			R=__ I=__ W=

CHANGE PRE-FILTER EVERY 6 MONTHS	FEB	AUG

*ROTATIONAL CLEANING SOLUTIONS : **PD** (PeridoxRTU)[DT=3 min], **PM *** (PREEMPT RTU Disinfectant)[DT= 10 min], **TBI*** (TBI 3300 Disinfectant)[DT=1 min] ***CLEANING** AGENT*

*ROTATIONAL CLEANING SCHEDULE: **TBI** ALTERNATE WITH **PM** WEEKLY.*

*MONTHLY CLEANING SOLUTIONS: **PD** ; WALL AND CEILING WITH PERIDOX AND ALCOHOL ONLY*

revised 11/01/2023

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/24/23		PA	PITTSBURGH	ALLEGHENY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
GD23-005321		COURT OF COMMON PLEAS ALLEGHENY County		
Reason/Charge				
COLLECTION Action ON Behalf OF POLARIS				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
POLARIS PHARMACY SERVICES			LAWSUIT	
Name of Business/Industry/Entity				
POLARIS PHARMACY Services OF PENNSYLVANIA, LLC.				

Provide explanation below:

Please see attached.

COLLECTIONS SUIT TO get ACCOUNTS RECEIVABLE.

Robert My

Original Signature (electronic, copies or stamps not accepted)

12/1/23

Date

MedPlus Pharmacy

335 Lindbergh Avenue
Livermore, CA 94551

Phone: (888) 222-8405
FEIN: 06-1643725
State Rx Lic: PHY58705

Officers

David Rombro (CEO)
[redacted]
Phone: (800) 589-9747
Email: drombro@polarisrx.com

Robert Meyer (CFO)
[redacted]
Phone: (800) 589-9747
Email: rmeyer@polarisrx.com

Steven Baker (COO)
[redacted]
Phone: (800) 589-9747
Email: sbaker@polarisrx.com

Ownership

MedPlus Pharmacy

- Owned by: Med-Plus Pharmacy, Inc.
  - *which is owned by*: Polaris Pharmacy Services of Los Angeles, LLC (100%)
    - *which is owned by*: Polaris Pharmacy Services of California, LLC (100%)
      - *which is Owned by*: Polaris Pharmacy Services, LLC (100%)

***all have same officers**

Polaris Pharmacy Services, LLC
2900 NW 60th Street
Fort Lauderdale, FL 33309

FEIN:	47-4098540
Owned by:	Da Pharmacy Guys, LLC (22.03%) Enhanced Medical Services (24.30) EJJ Pharma, LLC (24.30%) PPGRX North Carolina, LLC (29.37%)
Managers:	David W. Rombro, Daniel Galbut, Harold Sussman
Officers:	David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

Managers

David Rombro [redacted]
[redacted]NW 127 Way
Parkland, FL 33076
Phone: (800) 589-9747
Email: drombro@polarisrx.com

Daniel Galbut [redacted]
[redacted]N. 49th Avenue
Hollywood, FL 33021
Phone: [redacted]
Email: [redacted]

Harold Sussman [redacted]
[redacted]Avenue L
Brooklyn, NY 11230
Phone: [redacted]
Email: hsussman@kochingroup.com

Owners 5% or More

Name	DOB	SSN	% of Ownership
David Rombro [redacted]NW 127 Way Parkland, FL 33076	[redacted]		8.57%
Steve Baker [redacted]Bayshore Drive, Unit 803 Fort Lauderdale, FL 33304	[redacted]		7.34%
Todd Zisek [redacted]French Lace Drive Lutz, FL 33558	[redacted]		6.12%
Jonathan Paritzky [redacted]ndover Lane Woodmere, NY 11598	[redacted]		8.52%
Eric Galbut [redacted]N. Jefferson Avenue Miami Beach, FL 33140	[redacted]		5.38%
Daniel Galbut [redacted]N. 49th Avenue Hollywood, FL 33021	[redacted]		5.38%
Naftali Zanziper [redacted]Ave N. Brooklyn, NY 11210	[redacted]		7.34%
Simcha Hyman [redacted]Wesley Chapel Road Suffers, NY 10901	[redacted]		7.34%

Responsible agent for Board Communication

Gina Hunt
ghunt@polarisrx.com
[redacted]
[redacted]NW 60th Street
Fort Lauderdale, FL 33306

Renewal Certificate

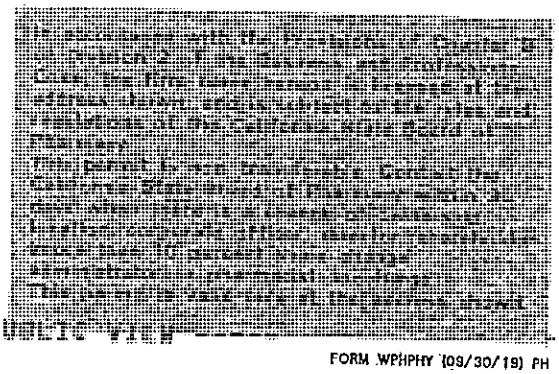
Retail Pharmacy Permit

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. PHY 58705
RECEIPT NO. 00186632

VALID UNTIL AUGUST 01, 2024

MED-PLUS PHARMACY
335 LINDBERGH AVE
LIVERMORE CA 94551



7/10/23
7/10/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PH

Renewal Certificate

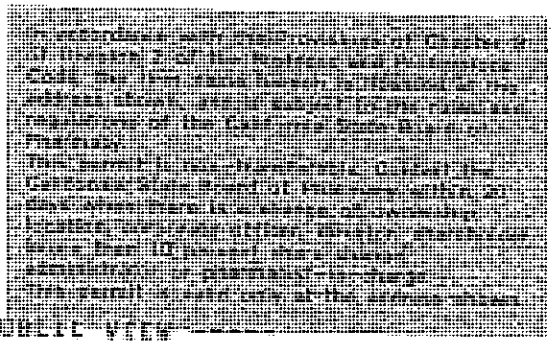
Sterile Compounding License

BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

LICENSE NO. LSC 101775
RECEIPT NO. 00186633

VALID UNTIL AUGUST 01, 2024

MED-PLUS PHARMACY
335 LINDGERGH AVE
LIVERMORE CA 94551



'11/23
'11/23

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

WPHLSC 09/30/1

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58705

NAME: MED-PLUS PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

335 LINDBERGH AVE
LIVERMORE CA 94551
ALAMEDA COUNTY

ISSUANCE DATE

AUGUST 31, 2022

EXPIRATION DATE

AUGUST 1, 2024

CURRENT DATE / TIME

JULY 11, 2023
7:32:20 AM

LICENSE RELATIONSHIPS

NAME: MED-PLUS PHARMACY

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101775 **PRIMARY STATUS:** CLEAR

ADDRESS :
335 LINDGERGH AVE
LIVERMORE CA 94551
ALAMEDA COUNTY

NAME: MA, YUKE

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 84345 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM2047757	01-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-08-2022

MED-PLUS PHARMACY
335 LINDBERGH AVE
LIVERMORE, CA 945519291

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM2047757	01-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	09-08-2022

MED-PLUS PHARMACY
335 LINDBERGH AVE
LIVERMORE, CA 945519291

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 6/14/2023 Inspector: Lesa Fitzpatrick

Firm: MED-PLUS PHARMACY Phone: (888) 222-8405

Address: 335 LINDGERGH AVE City: LIVERMORE Zip: 94551

Ownership: CORPORATION

Permit #: PHY58705 LSC101775 Permit Exp: 8/1/2023 DEA#: FM2047757 DEA Exp: 1/31/2025

Date of Self Assessment Form: 11/1/2022 Other Permit #: N/A Date of DEA Inventory: 5/2/2023

Hours M-F: 8AM to 12AM Hours Saturday: 8AM to 9:30PM Hours Sunday: 8AM to 9:30

PIC YUKE MA RPH84345 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:
TRISH D HO	RPH70245
ZI LI	RPH79317
JIAWEN ZENG	RPH82986
NICOLE D NGUYEN	RPH64897
JUDY W LAU	RPH85011
SHAWN N HO	RPH67015

Staff Name:	License #:
BERMUDA L KELLER	TCH26441
DARLENE A ERVIN	TCH166787
DARLENE A RODRIGUEZ	TCH140177
GRICELDA B BANQUIL	TCH134437
HIEN T NGUYEN	TCH177969
KATTIE G NEWELL	TCH169235
KITTIE PANNYASY	TCH187919
LINA G HAMMOUDEH	TCH178029
MARIA AIZZA P AQUINO	TCH131465
MARIA B NGUYEN	TCH19134
MARIA TOLENTINO	CLERK/TYPIST
MOHAMAD MASHOQ	TCH145317
NAZLHY GONZALEZ	CLERK/TYPIST
ROHY SAMIMI	TCH79961

Inspector Remarks:

Routine Inspection – Med Plus

Onsite inspection performed 6/14/23 with LSC 101775 annual renewal inspection. Assisted by RPH Li

PIC contact information: michelle.ma@medplusltc.com

Description of pharmacy: Closed door long- term care pharmacy that services skilled nursing facilities. Currently servicing 18 SNFs (no ALFS) Service area includes Sacramento, SF, Sebastopol area, and Stockton area. Volume of prescriptions filled daily (excluding CSPs): 400, meds packaged in bubble packs

Sterile compounding- non-HD See inspection for LSC 101775 for details. Average number of sterile- to- sterile products compounded daily: Very few. Uses premix bags and snaps whenever possible. 20-30 bags weekdays/4-6 bags weekend, mainly antibiotics.
Uses e-kits and ADDS machines (currently have 11 licensed Cubex units)
Have Dosis machine to fill fast movers
Delivery of meds by courier service
Pharmacist on call after hours

Confirmed pharmacists are subscribed to Board's email subscriber alerts

Outsourcers: CAPS for TPNs
Wholesaler: Amerisource Bergin, Numed, Parmed, various others
Reverse distributor: SMC returns, Reverse Distributors
Waste: Healthwise Services

Items observed:

- Original licenses for pharmacy and latest renewal
- Notice to Consumer

Items reviewed:

- Community and compounding self- assessments- 11/1/22
- Sink with hot and cold running water
- Pharmacists/Pharmacy Technicians wearing nametags with title in minimum 18 pt. font
- Ratios at time of the inspection: 1 RPH, 2 TCHs (one filling and one performing data entry) when I first arrived. During the inspection one more RPH arrived and one more TCH arrived
- Controlled drug Inventory- CII: 1/27/23, CIII-V: 10/12/22- see discussion
- CII Narcotic Reconciliation-last one that could be located during the inspection was performed 9/2022- see correction
- Power of Attorney
- No DEA 106 forms completed
- CII prescriptions received mainly electronically from prescribers
- CIII-CV invoices/CII invoices, 222's- filed separately
- Electronic 222 forms
- Security: badge access. The system will not allow techs to enter pharmacy floor unless a pharmacist is on duty. Security cameras present
- Refrigerator, pharmacy temps- reviewed with LSC 101775 renewal inspection
- Quarantine area for expired meds
- Patient Rx label- reviewed
- Policies and Procedures: theft and impairment, temp absence of a pharmacist. The compounding P/P's reviewed with LSC 101775 inspection

Discussion/Education:

- At the time of the inspection, the last CII quarterly narcotic reconciliation report that could be located was done in September of 2022. See correction
- When asked for the last controlled inventory I was given the 5/2/23 inventory performed by the inventory company. Please make sure if you are using for your biennial inventory it has all the required elements. The

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 6/14/2023

Permit #: PHY58705

Time of Day: ~~12:00 AM~~ 12:45 pm

Name as shown on permit: **MED-PLUS PHARMACY**

Address: 335 LINDGERGH AVE

City: LIVERMORE

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1715.65(c)(1)** Inventory Reconciliation Report of Controlled Substances. A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

In that at the time of the inspection the last CII quarterly reconciliation report that could be located was from 9/2022

Either perform a CII reconciliation or send a current one if it has been done recently. See action item

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) Lisa Fitzpatrick

Inspector (print) Lisa Fitzpatrick

Date 6/14/23

Signed [signature]

Print Name Zi Li

Title Pharmacist

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

ones I reviewed for 1/27/23 (CII's) and 10/12/22 (CIII-V) were compliant.

- CCR 1732.5(b) Renewal Requirements for Pharmacists:
  - At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethicshttps://www.pharmacy.ca.gov/licensees/webinars/law_2021/2021_law_webinar.html
- For questions pertaining to pharmacy law, please contact the board Monday through Thursday from 9am to 1pm. Email: ask.inspector@dca.ca.gov (Include name, organization, phone, and best time to call) Fax: (916) 574-8618 Phone: (916) 518-3100
- New laws for 2023: Be aware of **statutory changes in Pharmacy Law that took effect in 2023- https://www.pharmacy.ca.gov/laws_regs/new_laws.pdf**
- Law book: **https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf**

Action items:

- Perform a current CII quarterly reconciliation inventory and send to Inspector Fitzpatrick or if a current one was completed then send that one.- see correction

Send action item to Inspector Fitzpatrick by end of business 6/28/23.
Please keep a signed copy of this inspection report on file and readily available for three years.
Inspector Fitzpatrick
Lesa.fitzpatrick@dca.ca.gov
(707)771-5113

"Pursuant to Business and Professions Code 4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of corrections, for an office conference with the board's executive officer to contest the order of correction."

Licensee Remarks:

I have reviewed, discussed, understand and received a copy of this form.

Pharmacist (sign) Zi Li
Pharmacist (print) Zi Li

Inspector (sign) Lesa Fitzpatrick
Inspector (print) Lesa Fitzpatrick

Owner(sign) _____
Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance ontcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

Jackie Le

From: Michelle(Yuke) Ma <michelle.ma@medplusltc.com>
Sent: Friday, August 4, 2023 9:07 PM
To: Jackie Le
Subject: Fw: Inspection document request LSC 101775
Attachments: C2 Reconciliation 2023.xlsx

Please see below for the corrective actions I sent to the BOP.

Thank you,
Michelle

Michelle (Yuke) Ma, PharmD
Pharmacist-in-Charge
Med-Plus Pharmacy, a Polaris Pharmacy Services Company
Ph: (888)222-8405 ext 3999
Cell: [redacted]
Fax: (866)530-2069
mma@polarisrx.com
michelle.ma@medplusltc.com

MED-PLUS PHARMACY, INC
a Polaris Pharmacy Services company

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From: Michelle(Yuke) Ma <michelle.ma@medplusltc.com>
Sent: Friday, June 23, 2023 3:14 PM
To: Fitzpatrick, Lesa@DCA <Lesa.Fitzpatrick@dca.ca.gov>
Cc: Darlene Ervin <darlene.ervin@medplusltc.com>; Flynn Lew <flynn.lew@medplusltc.com>; Sudeen Douglas <sdouglas@polarisrx.com>
Subject: Re: Inspection document request LSC 101775

Good afternoon Inspector Fitzpatrick,

Thank you for spending time with us and doing the inspection on 06/14/2023. Please see attachment for the C2 Reconciliation you requested. This EXCEL sheet contains all C2 reconciliation from Jan 2023 to May 2023. If

you have any questions or needing any additional information, please reach out to me anytime at 510-940-3520 or email me at michelle.ma@medplusltc.com.

Again, thank you for your help. I hope you have a wonderful day

Best regards,
Michelle

Michelle (Yuke) Ma, PharmD
Pharmacist-in-Charge
Med-Plus Pharmacy, a Polaris Pharmacy Services Company
Ph: (888)222-8405 ext 3999
Cell: [redacted]
Fax: (866)530-2069
mma@polarisrx.com
michelle.ma@medplusltc.com

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From: Fitzpatrick, Lesa@DCA <Lesa.Fitzpatrick@dca.ca.gov>
Sent: Wednesday, May 10, 2023 3:12 PM
To: Michelle(Yuke) Ma <michelle.ma@medplusltc.com>
Cc: Darlene Ervin <darlene.ervin@medplusltc.com>; Trish Ho <trish.ho@medplusltc.com>
Subject: RE: Inspection document request LSC 101775

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Thank you for sending Michelle.. Unfortunately at this time I am unable to tell you when the inspection will be.

Thank you,

Lesa

Lesa Fitzpatrick, RPh
Inspector
California State Board of Pharmacy
(707) 771-5113 | FAX (707)745-0104 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!
Lawbook: https://pharmacy.ca.gov/laws_regs/lawbook.pdf

From: Michelle(Yuke) Ma <michelle.ma@medplusltc.com>
Sent: Monday, May 8, 2023 4:17 PM
To: Fitzpatrick, Lesa@DCA <Lesa.Fitzpatrick@dca.ca.gov>
Cc: Darlene Ervin <darlene.ervin@medplusltc.com>; Trish Ho <trish.ho@medplusltc.com>
Subject: Re: Inspection document request LSC 101775

WARNING: This message was sent from outside the CA Gov network. Do not open attachments unless you know the sender: michelle.ma@medplusltc.com

Good Afternoon Inspector Fitzpatrick,

Thank you for patiently waiting. I have all the documents submitted on the same share drive. Please see below for the link and password for the information you requested. If you have any questions, or having any difficulties opening the share drive, please let me know immediately.

LSC 101775 Inspection Documents
Password: Medplus123!

Also, would you be able to tell us when the inspection is scheduled?

Best regards,
Michelle

Michelle (Yuke) Ma, PharmD
Pharmacist-in-Charge
Med-Plus Pharmacy, a Polaris Pharmacy Services Company
Ph: (888)222-8405 ext 3999
Cell: [redacted]
Fax: (866)530-2069
mma@polarisrx.com
michelle.ma@medplusltc.com

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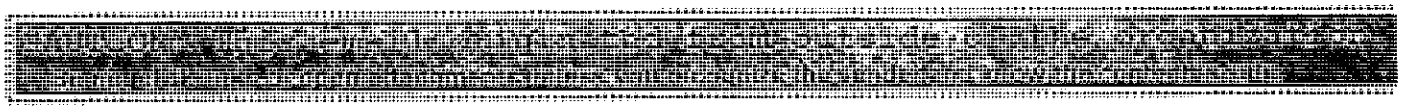
From: Fitzpatrick, Lesa@DCA <Lesa.Fitzpatrick@dca.ca.gov>
Sent: Tuesday, April 25, 2023 10:40 AM
To: Michelle(Yuke) Ma <michelle.ma@medplusllc.com>
Subject: Inspection document request LSC 101775



Good Morning PIC Ma,

I am the inspector assigned to perform the renewal for LSC 101775. In preparation for the inspection please send the following items electronically by end of business 5/9/23:

1. Compounding self- assessment and current list of staff
2. Community self-assessment
3. Any changes to the sterile compounding policies and procedures since last inspection
4. Wholesaler, Reverse Distributor, and Waste Company used
5. Any FDA, DEA, and/or accreditation inspections with applicable reports issued within the past 12 months and responses if applicable
6. DEA license expiration date and date of last control drug inventory
7. Volume of sterile products compounded daily. Where applicable also indicate HD and non-HD volume separately
8. Describe any changes to the physical layout of the sterile compounding facilities and any changes in the sterile compounding equipment since last inspection
9. Describe any changes in the types of sterile products compounded at your facility since the last inspection. (For example, risk level changes or hazardous versus non-hazardous products)
10. Any changes to the list of sterile medications compounded at your facility since the last inspection
11. The most recent certification records for all ISO certified areas with smoke pattern videos for all ISO 5 spaces. (If the smoke video files are too large to send electronically, please confirm in writing that you have them available)
12. The most recent environmental air and surface viable sampling. If out of compliance growth detected during sampling please provide pharmacy's action plan in response.
13. Records:

a. Compounding worksheets/ master formulas/ labels for 4 compounded sterile products (CSPs). Please provide a variety of risk categories if available
b. All cleaning logs for hoods and rooms for the past two months. Please provide germicidal, disinfecting, and sporicidal agents used and if applicable decontamination agent used
c. Sterile compounding equipment calibration and maintenance logs for the past two months if applicable
d. Pressure differential monitoring logs for the past two months.
e. Refrigerator/freezer/incubator temperature logs for the past two months
f. Room temperature logs for the past two months

14. Employee competencies for compounding staff (one RPH and one TCH), such as didactic training, pharmaceutical calculations, gloved fingertip sampling, media fill testing, practical skills training in aseptic area practices, cleaning, etc.
15. Qualitative/quantitative analysis results for CSPs performed in the past 12 months
16. Any adverse events (ADR) or recalls related to your CSPs since last inspection

Thank you,

Lesa

Lesa Fitzpatrick, RPh
Inspector
California State Board of Pharmacy
(707) 771-5113 | FAX (707)745-0104 | www.pharmacy.ca.gov

Be Aware and Take Care: Talk to your Pharmacist!

Lawbook: **https://pharmacy.ca.gov/laws_regs/lawbook.pdf**

Med-Plus Pharmacy Livermore
335 Lindberg Ave, Livermore, CA 94551
DEA # FM2047757
Reconciliation Date: 01/27/2023
Reconciliated by: Michelle (Yuke) Ma

Schedule II Control Substances Inventory Reconciliation Report

					ACQUISITIONS						DISPOSITIONS											
DEA CLASS	ITEM DESCRIPTION	NDC	Date of Last Count	Quantity at Last Count	Total Purchases	MFG Overfill	Total RTS (filled prior to last count)	Total Interpharmacy Transfer-In	Total ADDS/Ekit Returns	Total Acquisitions	Total Dispensed	Total E-kit Usage	ADDS Usage	Total Claim Reversal	Total Interpharmacy Transfer-Out	Reverse Distributor	Damaged	Expired for Reverse Distributor	Total Dispositions	EQUALS: Expected On-hand Quantity	Actual On-hand Count	Variance	Explanation of Variance
2	Dextroamphetamine/Amphetamine 5mg Tablet	00406-8891-01	12/21/2022	200						0									0	200	200		
2	Dextroamphetamine/Amphetamine 5mg ER Tabley	66993-0594-02	12/21/2022	76						0									0	76	76		
2	Dextroamphetamine/Amphetamine 10mg ER Tablet	49884-0840-01	12/21/2022	16						0									0	16	16		
2	Dextroamphetamine 10mg Tablet	00555-0953-02	12/21/2022	155						0									0	155	155		
2	Dextroamphetamine/Amphetamine 20mg Tablet	00555-0973-02	12/21/2022	12						0									0	12	12		
2	Dextroamphetamine/Amphetamine 15mg ER Capsule	66993-0596-02	12/21/2022	76						0									0	76	76		
2	Dextroamphetamine/Amphetamine 30mg Tablet	13107-0074-01	12/21/2022	86						0									0	86	86		
2	Dextroamphetamine/Amphetamine 30mg ER Tablet	00115-1491-01	12/21/2022	86						0									0	86	86		
2	Hydromorphone 2mg Tablet	42858-0301-01	12/21/2022	1461						0	767			42					725	736	736		
2	Hydromorphone 4mg Tablet	42858-0302-01	12/21/2022	629						0	249								249	380	380		
2	Hydromorphone 8mg Tablet	42858-0303-01	12/21/2022	263						0	144								144	119	119		
2	Hydromorphone 16mg ER Tablet	13811-0703-10	12/21/2022	93						0									0	93	93		
2	Methadone 5mg Tablet	00054-0709-25	12/21/2022	1222						0	557								557	665	665		
2	Methadone 10mg Tablet	00406-5771-01	12/21/2022	500	300					300	426								426	374	374		
2	Methadone 10mg Tablet	00054-0710-25	12/21/2022	391						0	391								391	0	0		
2	Methylphenidate 5mg Tablet	16729-0478-01	12/21/2022	190						0									0	190	190		
2	Methylphenidate 10mg Tablet	10702-0101-01	12/21/2022	100						0									0	100	100		
2	Methylphenidate 20mg Tablet	57664-0230-88	12/21/2022	79							42								42	37	37		
2	Methylphenidate 20mg ER Tablet	00406-1473-01	12/21/2022	86																86	86		
2	Methylphenidate 36mg ER Tablet	31722-0954-01	12/21/2022	93																93	93		
2	Morphine 10mg ER Capsule	00832-0225-00	12/21/2022	138																138	138		
2	Morphine 15mg ER Tablet	00406-8315-01	12/21/2022	136	1000					1000	957								957	179	179		
2	Morphine 15mg ER Tablet	42858-0801-01	12/21/2022	7							7								7	0	0		
2	Morphine 15mg Tablet	00054-0235-25	12/21/2022	154	500					500	275								275	379	379		
2	Morphine 30mg Tablet	00054-0236-25	12/21/2022	464																464	464		
2	Morphine 30mg ER Tablet	00406-8330-01	12/21/2022	398	500					500	354								354	544	544		
2	Morphine 30mg ER Capsules	00832-0227-00	12/21/2022	155																155	155		
2	Morphine 60mg ER Tablet	42858-0803-01	12/21/2022	283							53								53	230	230		
2	Morphine 100mg ER Tablet	42858-0804-01	12/21/2022	288																288	288		
2	Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-01	12/21/2022	2000	11000					11000	10832			38					10794	2206	2206		
2	Hydrocodone/Acetaminophen 5/300mg Tablet	42858-0040-01	12/21/2022	100																100			
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	71930-0020-12	12/21/2022	4																4	4		
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	00406-0124-01	12/21/2022	4																4	4		
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	00406-0124-65	12/21/2022	698							317								317	381	381		
2	Hydrocodone/Acetaminophen 10/325mg Tab	00406-0125-01	12/21/2022	1526	4000	1				4001	4405			63					4342	1185	1185		
2	Oxycodone 5mg Capsule	62559-0167-01	12/21/2022	102	300					300	343			30					313	89	89		
2	Oxycodone 5mg Tablet	00406-0552-01	12/21/2022	2550	10000					10000	10026			56					9970	2580	2580		
2	Oxycodone 10mg Tablet	10702-0056-01	12/21/2022	0	2000					2000	808								808	1192	1192		
2	Oxycodone 10mg Tablet	65162-0048-10	12/21/2022	0	800					800	700		100						800	0	0		
2	Oxycodone 10mg Tablet	42858-0002-01	12/21/2022	667							667								667	0	0		
2	Oxycodone 15mg Tablet	00406-8515-01	12/21/2022	334	500					500	169								169	665	665		
2	Oxycodone 20mg Tablet	42858-0004-01	12/21/2022	262							135								135	127	127		
2	Oxycodone 20mg Tablet	10702-0057-01	12/21/2022	6							6								6	0	0		
2	Oxycodone 30mg Tablet	00406-8580-01	12/21/2022	246	200					200	30								30	416	416		
2	Oxycontin 10mg Tablet (Brand)	59011-0410-10	12/21/2022	145																145	145		
2	Oxycodone 10mg ER Tablet	69238-2294-01	12/21/2022	328							264								264	64	64		
2	Oxycontin 15mg Tablet (Brand)	59011-0415-10	12/21/2022	141																141	141		
2	Oxycodone 20mg ER Tablet	69238-2296-01	12/21/2022	86							60								60	26	26		
2	Oxycodone 20mg ER Tablet	00093-5732-01	12/21/2022	4																4	4		
2	Oxycontin 30mg CR Tablet (Brand)	59011-0430-10	12/21/2022	337																337	337		
2	Oxycontin 40mg CR Tablet (Brand)	59011-0440-10	12/21/2022	100																100	100		
2	Oxycodone 40mg ER Tablet	00093-5733-01	12/21/2022	54																54	54		
2	Oxycontin 60mg CR Tablet (Brand)	49011-0460-10	12/21/2022	100																100	100		
2	Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-01	12/21/2022	905	2000					2000	2044								2044	861	861		
2	Oxycodone/Acetaminophen 5/325mg Tablet	42858-0102-01	12/21/2022	0	300					300										300	300		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	47781-0229-01	12/21/2022	396							131								131	265	265		
2	Oxycodone/Acetaminohen 10/325mg Tablet	42858-0104-50	12/21/2022	0	1500					1500	179								179	1321	1321		
2	Oxycodone/Acetaminohen 10/325mg Tablet	42858-0104-01	12/21/2022	0	500					500	526			30					496	4	4		
2	Oxycodone/Acetaminophen 10/325mg Tablet	00405-0523-01	12/21/2022	1205							1205								1205	0	0		
2	Xtampza 9mg ER Capsule	24510-0110-10	12/21/2022	72																72	72		
2	Xtampza 13.5mg ER Capsule	24510-0115-10	12/21/2022	23																23	23		
2	Xtampza 18mg ER Capsule	24510-0120-10	12/21/2022	100																100	100		
2	Fentanyl 12mcg/hr Patch	00406-9112-76	12/21/2022	0	15					15										15	15		
2	Fentanyl 12mcg/hr Patch	00378-9119-98	12/21/2022	13							10								10	3	3		
2	Fentanyl 25mcg/hr Patch	00406-9125-76	12/21/2022	15	10					10	18								18	7	7		
2	Fentanyl 25mcg/hr Patch	60505-7081-02	12/21/2022	5							4								4	1	1		
2	Fentanyl 25mcg/hr Patch	00378-9121-98	12/21/2022	1																1	1		
2	Fentanyl 50mcg/hr Patch	00406-9150-76	12/21/2022	12	10					10	12								12	10	10		
2	Fentanyl 50mcg/hr Patch	00378-9122-98	12/21/2022	3	15					15	3								3	15	15		
2	Fentanyl 75mcg/hr Patch	00378-0912-98	12/21/2022	0	15					15										15	15		
2	Fentanyl 75mcg/hr Patch	00505-7083-02	12/21/2022	12							11								11	1	1		
2	Fentanyl 100mcg/hr Patch	00378-9124-98	12/21/2022	15																15	15		
2	Fentanyl 100mcg/hr Patch	60505-7084-02	12/21/2022	5																5	5		
2	Hydrocodone/Acetaminophen 7.5/325mg/15mL Solution	71930-0027-43	12/21/2022	886	473					473	473								473	886	886		
2	Hydromorphone 1mg/mL Solution	42858-0304-16	12/21/2022	639							80								80	559	559		

2 Methadone 5mg/5mL Oral Solution	00054-3555-63	12/21/2022	990										990	990	
2 Methadone 10mg/mL Oral Solution	00054-3553-44	12/21/2022	53				30					30	23	23	
2 Methadone 10mg/5mL Oral Solution	00054-3556-63	12/21/2022	500										500	500	
2 Lortab 10/300mg/15mL Oral Solution	17478-0450-16	12/21/2022	969										969	969	
2 Morphine 100mg/5mL Oral Solution (15ml Package Size)	00054-0517-41	12/21/2022	450	150		150	245					245	355	355	
2 Morphine 100mg/5mL Oral Solution (30mL Package Size)	00054-0517-44	12/21/2022	510				240			90		150	360	360	
2 Morphine 10mg/5mL Oral Solution	00054-0237-63	12/21/2022	500	1000		1000	450					451	1049	1065	16 Fluid Variation
2 Oxycodone 100mg/5mL Oral Solution	71930-0023-30	12/21/2022	30										30	30	
2 Oxycodone 5mg/5mL Oral Solution	62559-0151-16	12/21/2022	1975										1975	1975	
2 Hydromorphone 2mg/mL Injection	00409-3365-10	12/21/2022	40					10	10			20	20	20	
2 Morphine 5mg/10mL Injection	00409-3814-12	12/21/2022	40										40	40	
2 Morphine 10mg/mL Injection	00641-6127-25	12/21/2022	53						3			3	50	50	
2 Morphine 4mg/mL Injection	00641-6125-25	12/21/2022	0	25		25							25	25	
E-Kit Inventory															
2 Hydromorphone 2mg/mL Injection	00409-3365-11	12/21/2022	0		10	10					1	1	9	9	
2 Hydromorphone 2mg Tablet	60687-0579-11	12/21/2022	48					3				3	45	45	
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	12/21/2022	84	100		100		55	30			85	99	99	
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	12/21/2022	17										17	17	
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	12/21/2022	50	100		100		25			22	47	103	103	
2 Morphine 10mg/mL Injection	00641-6127-25	12/21/2022	3										3	3	
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	12/21/2022	24					2				2	22	22	
2 Morphine 15mg Tablet	00054-0235-24	12/21/2022	78					11				11	67	67	
2 Morphine 15mg Tablet	00054-0235-25	12/21/2022	2		12	12		2			12	14	0	0	
2 Oxycodone 5mg Tablet	00406-0552-01	12/21/2022	6		100	100		44				44	62	62	
2 Oxycodone 10mg Tablet	68084-0968-01	12/21/2022	0	200		200							200	200	
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	12/21/2022	0	100		100			100			100	0	0	
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	12/21/2022	62					12	20			32	30	30	
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-01	12/21/2022	65	100		100		74	30			104	61	61	
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0230-01	12/21/2022	9		66	66					75	75	0	0	
CUBEX Inventory															
2 Hydromorphone 2mg Tablet	60687-0579-01	12/21/2022	55		4	4			40			40	19	19	
2 Hydromorphone 2mg/mL Injection	00409-3365-11	12/21/2022	2		12	12			10			10	4	4	
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	12/21/2022	0	200	60	260		100	90			190	70	70	
2 Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-23	12/21/2022	15		11	11			10			10	16	16	
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	12/21/2022	13		14	14					14	14	13	13	
2 Hydrocodone/Acetaminophen 10/325mg Tab	53746-0110-05	12/21/2022	31		10	10			30			30	11	11	
2 Methadone 5mg Tablet	00406-5755-62	12/21/2022	76						30			30	46	46	
2 Methadone 10mg Tablet	00054-0710-20	12/21/2022	0	100		100							100	100	
2 Morphine 15mg Tablet	00054-0235-25	12/21/2022	34						30			30	4	4	
2 Morphine 10mg/mL Injection	00641-6127-25	12/21/2022	5		9	9			10			10	4	4	
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	12/21/2022	44		3	3			15			15	32	32	
2 Oxycodone 5mg Tablet	47781-0263-05	12/21/2022	2										2	2	
2 Oxycodone 5mg Tablet	00406-0552-23	12/21/2022	49	100	72	172		100	110		4	214	7	7	
2 Oxycodone 5mg Tablet	00904-6966-61	12/21/2022	4										4	4	
2 Oxycodone 10mg Tablet	65162-0048-10	12/21/20222	0		110	110			80			80	30	30	
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	12/21/2022	0		106	106			50		6	56	50	50	
2 Oxycodone/Acetaminophen 5/325mg Tablet	47780-0196-01	12/21/2022	9										9	9	
2 Oxycodone/Acetaminophen 5/325mg Tablet	50268-0644-11	12/21/2022	2		17	17					17	17	2	2	
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	12/21/2022	20		30	30			40			40	10	10	
2 Oxycodone/Acetaminophen 10/325mg Tablet	47781-0230-01	12/21/2022	20		2	2			16		4	20	2	2	
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-11	12/21/2022	0	100	30	130			24			24	106	106	

Med-Plus Pharmacy Livermore
335 Lindberg Ave, Livermore, CA 94551
DEA # FM2047757
Reconciliation Date: 04/01/2023
Reconciliated by: Michelle (Yuke) Ma

Schedule II Control Substances Inventory Reconciliation Report

DEA CLASS	ITEM DESCRIPTION	NDC	Date of Last Count	Quantity at Last Count	ACQUISITIONS					DISPOSITIONS								EQUALS: Expected On-hand Quantity	Actual On-hand Count	Variance	Explanation of Variance
					Total Purchases	MFG Overfill	Total RTS (filled prior to last count)	Total Interpharmacy Transfer-In	Total ADDS/EAS Rebills	Total Acquisitions	Total Dispensed	Total Exit Usage	ADDS Usage	Total Claim Reversal	Total Interpharmacy Transfer-Out	Reverse Distributor	Damaged	Expired for Reverse Distributor	Total Dispositions				
2	Dextroamphetamine/Amphetamine 5mg Tablet	00406-8891-01	03/05/2023	193						0								0	193	193		
2	Dextramphetamine 5mg Tablet	00406-8958-01	03/05/2023	0	100					100	30							30	70	70		
2	Dextroamphetamine/Amphetamine 5mg ER Tabley	66993-0594-02	03/05/2023	76						0								0	76	76		
2	Dextroamphetamine/Amphetamine 10mg ER Tablet	49884-0840-01	03/05/2023	16						0								0	16	16		
2	Dextroamphetamine 10mg Tablet	00555-0953-02	03/05/2023	127						0							127	127	0	0		
2	Dextroamphetamine/Amphetamine 20mg Tablet	00555-0973-02	03/05/2023	12						0								0	12	12		
2	Dextroamphetamine/Amphetamine 15mg ER Capsule	66993-0596-02	03/05/2023	16						0								0	16	16		
2	Dextroamphetamine/Amphetamine 30mg Tablet	13107-0074-01	03/05/2023	86						0								0	86	86		
2	Dextroamphetamine/Amphetamine 30mg ER Tablet	00115-1491-01	03/05/2023	86						0								0	86	86		
2	Hydromorphone 2mg Tablet	00406-3243-01	03/05/2023	566	1600					1600	1403	100		30				1473	693	693		
2	Hydromorphone 4mg Tablet	42858-0302-01	03/05/2023	364			21			21	377							377	8	8		
2	Hydromorphone 4mg Tablet	00406-3244-01	03/05/2023	0	1000					1000	804							804	196	196		
2	Hydromorphone 8mg Tablet	42858-0303-01	03/05/2023	7						0								0	7	7		
2	Hydromorphone 8mg Tablet	00406-3249-01	03/05/2023	100						0								0	100	100		
2	Hydromorphone 18mg ER Tablet	13811-0703-10	03/05/2023	93						0								0	93	93		
2	Methadone 5mg Tablet	00054-0709-25	03/05/2023	275						0	272						1	273	2	2		
2	Methadone 5mg Tablet	00406-5755-01	03/05/2023	1000						0	154							154	846	846		
2	Methadone 10mg Tablet	00406-5771-01	03/05/2023	824	300					300	881							881	243	243		
2	Methylphenidate 5mg Tablet	16729-0478-01	03/05/2023	190						0								0	190	190		
2	Methylphenidate 10mg Tablet	10702-0101-01	03/05/2023	100						0	74							74	26	26		
2	Methylphenidate 10mg Tablet	00406-1164-01	03/05/2023	0	200					200								0	200	200		
2	Methylphenidate 20mg Tablet	57664-0230-88	03/05/2023	137															137	137		
2	Methylphenidate 20mg ER Tablet	00406-1473-01	03/05/2023	86															86	86		
2	Methylphenidate 36mg ER Tablet	31722-0954-01	03/05/2023	93															93	93		
2	Morphine 10mg ER Capsule	00832-0225-00	03/05/2023	138															138	138		
2	Morphine 15mg ER Tablet	00406-8315-01	03/05/2023	171	1500					1500	731			49				682	989	989		
2	Morphine 15mg Tablet	00054-0235-25	03/05/2023	347	300		8			308	193							193	462	462		
2	Morphine 20mg ER Capsules	00832-0226-00	03/05/2023	142															142	142		
2	Morphine 30mg Tablet	00054-0236-25	03/05/2023	464															464	464		
2	Morphine 30mg ER Tablet	00406-8330-01	03/05/2023	767							152							152	615	615		
2	Morphine 30mg ER Capsules	00832-0227-00	03/05/2023	155															155	155		
2	Morphine 60mg ER Tablet	42858-0803-01	03/05/2023	39							21							21	18	18		
2	Morphine 60mg ER Tablet	00406-8380-01	03/05/2023	200							56							56	144	144		
2	Morphine 100mg ER Tablet	42858-0804-01	03/05/2023	288							21							21	267	267		
2	Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-01	03/05/2023	1992	5500					5500	5928			157				5771	1721	1721		
2	Hydrocodone/Acetaminophen 5/300mg Tablet	42858-0040-01	03/05/2023	80															80	80		
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	71930-0020-12	03/05/2023	4															4	4		
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	00406-0124-01	03/05/2023	304							206							206	98	98		
2	Hydrocodone/Acetaminohen 7.5/325mg Tab	00406-0124-65	03/05/2023	19															19	19		
2	Hydrocodone/Acetaminophen 10/325mg Tab	00406-0125-01	03/05/2023	1165	3500					3500	4004			5				3999	666	666		
2	Oxycodone 5mg Capsule	62559-0167-01	03/05/2023	252							40							40	212	212		
2	Oxycodone 5mg Tablet	00406-0552-01	03/05/2023	952	8000					8000	7632		100	144				7588	1364	1364		
2	Oxycodone 10mg Tablet	10702-0056-01	03/05/2023	400	2100					2100	1637			10				1627	873	873		
2	Oxycodone 10mg Tablet	00406-8510-01	03/05/2023	448			6			6	452							452	2	2		
2	Oxycodone 15mg Tablet	00406-8515-01	03/05/2023	267	300					300	153							153	414	414		
2	Oxycodone 20mg Tablet	00406-8520-01	03/05/2023	0	100					100	72							72	28	28		
2	Oxycodone 20mg Tablet	42858-0004-01	03/05/2023	79	300					300	74							74	305	305		
2	Oxycodone 30mg Tablet	00406-8580-01	03/05/2023	416							28			14				14	402	402		
2	Oxycontin 10mg Tablet (Brand)	59011-0410-10	03/05/2023	67	500					500	374							374	193	193		
2	Oxycodone 10mg ER Tablet	69238-2294-01	03/05/2023	0															0	0		
2	Oxycontin 15mg Tablet (Brand)	59011-0415-10	03/05/2023	141							28			14				14	127	127		
2	Oxycontin CR 20mg Tablet (Brand)	59001-0420-10	03/05/2023	216	200					200	144							144	272	272		
2	Oxycodone 20mg ER Tablet	00093-5732-01	03/05/2023	4															4	4		
2	Oxycontin 30mg CR Tablet (Brand)	59011-0430-10	03/05/2023	337							42							42	295	295		
2	Oxycontin 40mg CR Tablet (Brand)	59011-0440-10	03/05/2023	100															100	100		
2	Oxycodone 40mg ER Tablet	69238-2298-01	03/05/2023	0	200					200									200	200		
2	Oxycodone 40mg ER Tablet	00093-5733-01	03/05/2023	54							42			14				28	26	26		
2	Oxycontin 60mg CR Tablet (Brand)	49011-0460-10	03/05/2023	100															100	100		
2	Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-01	03/05/2023	333	1500					1500	1078							1078	755	755		
2	Oxycodone/Acetaminophen 5/325mg Tablet	42858-0102-01	03/05/2023	300							129							129	171	171		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	47781-0229-01	03/05/2023	190							96							96	94	94		
2	Oxycodone/Acetaminohen 10/325mg Tablet	42858-0104-50	03/05/2023	272							267							267	5	5		
2	Oxycodone/Acetaminohen 10/325mg Tablet	42858-0104-01	03/05/2023	4	1600					1600	844							844	760	760		
2	Xtampza 9mg ER Capsule	24510-0110-10	03/05/2023	72													72	72	0	0		
2	Xtampza 13.5mg ER Capsule	24510-0115-10	03/05/2023	23															23	23		
2	Xtampza 18mg ER Capsule	24510-0120-10	03/05/2023	100															100	100		
2	Fentanyl 12mcg/hr Patch	00406-9112-76	03/05/2023	7	15					15	9							9	13	13		
2	Fentanyl 12mcg/hr Patch	00378-9119-98	03/05/2023	1															1	1		
2	Fentanyl 25mcg/hr Patch	00406-9125-76	03/05/2023	2							2							2	0	0		
2	Fentanyl 25mcg/hr Patch	60505-7081-02	03/05/2023	1															1	1		
2	Fentanyl 25mcg/hr Patch	00378-9121-98	03/05/2023	6	25					25	12							12	19	19		

2 Fentanyl 50mcg/hr Patch	00406-9150-76	03/05/2023	3										3	3
2 Fentanyl 50mcg/hr Patch	00378-9122-98	03/05/2023	5	25		25	13					13	17	17
2 Fentanyl 75mcg/hr Patch	00378-0912-98	03/05/2023	12										12	12
2 Fentanyl 100mcg/hr Patch	00378-9124-98	03/05/2023	15										15	15
2 Fentanyl 100mcg/hr Patch	60505-7084-02	03/05/2023	5										5	5
2 Hydrocodone/Acetaminophen 7.5/325mg/15mL Solution	71930-0027-43	03/05/2023	886	946		946	1419					1419	413	413
2 Hydromorphone 1mg/mL Solution	42858-0304-16	03/05/2023	559				30				56	86	473	473
2 Methadone 5mg/5mL Oral Solution	00054-3555-63	03/05/2023	990				210					210	780	780
2 Methadone 10mg/mL Oral Solution	00527-1927-36	03/05/2023	0	150		150							150	150
2 Methadone 10mg/mL Oral Solution	00054-3553-44	03/05/2023	23								23	23	0	0
2 Methadone 10mg/5mL Oral Solution	00054-3556-63	03/05/2023	500								500	500	0	0
2 Lortab 10/300mg/15mL Oral Solution	17478-0450-16	03/05/2023	946										946	946
2 Morphine 100mg/5mL Oral Solution (15ml Package Size)	00054-0517-41	03/05/2023	430				140					140	290	290
2 Morphine 100mg/5mL Oral Solution (30mL Package Size)	00406-8003-30	03/05/2023	180										180	180
2 Morphine 100mg/5mL Oral Solution (30mL Package Size)	00054-0517-44	03/05/2023	285				60					60	225	225
2 Morphine 10mg/5mL Oral Solution	00054-0237-63	03/05/2023	530	1000		1000	458			100		358	1172	1172
2 Oxycodone 100mg/5mL Oral Solution	71930-0023-30	03/05/2023	30										30	30
2 Oxycodone 5mg/5mL Oral Solution	62559-0151-16	03/05/2023	1975										1975	1975
2 Hydromorphone 2mg/mL Injection	00409-3365-10	03/05/2023	20					10				10	10	10
2 Morphine 5mg/10mL Injection	00409-3814-12	03/05/2023	40										40	40
2 Morphine 10mg/mL Injection	00641-6127-25	03/05/2023	50					25	2			27	23	23
2 Morphine 4mg/mL Injection	00641-6125-25	03/05/2023	25										25	25
E-Kit Inventory														
2 Hydromorphone 2mg/mL Injection	00409-3365-11	03/05/2023	6		10	10					8	8	8	8
2 Hydromorphone 2mg Tablet	00406-3243-01	03/05/2023	0		40	40		32				32	8	8
2 Hydromorphone 2mg Tablet	60687-0579-11	03/05/2023	22		26	26		30				30	18	18
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	03/05/2023	55	100	10	110		43	30			73	92	92
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	03/05/2023	17										17	17
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	03/05/2023	91					38	30			68	23	23
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	03/05/2023	19					11			8	19	0	0
2 Morphine 10mg/mL Injection	00641-6127-25	03/05/2023	2		25	25		5				5	22	22
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	03/05/2023	17		10	10		11			15	26	1	1
2 Morphine 15mg Tablet	00054-0235-24	03/05/2023	52	100		100		58	20			78	74	74
2 Morphine 15mg Tablet	00054-0235-25	03/05/2023	8		28	28					30	30	6	6
2 Oxycodone 5mg Tablet	00904-6966-61	03/05/2023	7		21	21							28	28
2 Oxycodone 5mg Tablet	47784-0263-05	03/05/2023	0		5	5		5				5	0	0
2 Oxycodone 5mg Tablet	00406-0552-01	03/05/2023	0		57	57		57				57	0	0
2 Oxycodone 5mg Tablet	68084-0354-01	03/05/2023	18	100	5	105		25				25	98	98
2 Oxycodone 10mg Tablet	68084-0968-01	03/05/2023	200						200			200	0	0
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	03/05/2023	100					30				30	70	70
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	03/05/2023	17					5				5	12	12
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-01	03/05/2023	26	100	30	130		65				65	91	91
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0230-01	03/05/2023	18		35	35					46	46	7	7
CUBEX Inventory														
2 Hydromorphone 2mg Tablet	00406-3243-01	03/05/2023	0		80	80			50			50	30	30
2 Hydromorphone 2mg Tablet	60687-0579-01	03/05/2023	19		12	12		8	20			28	3	3
2 Hydromorphone 2mg/mL Injection	00409-3365-11	03/05/2023	6		2	2			2			2	6	6
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	03/05/2023	16		51	51			40			40	27	27
2 Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-23	03/05/2023	10		31	31			20			20	21	21
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	03/05/2023	0		10	10							10	10
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	03/05/2023	0		40	40			30			30	10	10
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	03/05/2023	46		18	18			20		9	29	35	35
2 Hydrocodone/Acetaminophen 10/325mg Tab	53746-0110-05	03/05/2023	1		13	13							14	14
2 Methadone 5mg Tablet	00406-5755-62	03/05/2023	54		10	10			10			10	54	54
2 Methadone 10mg Tablet	00054-0710-20	03/05/2023	100										100	100
2 Morphine 15mg Tablet	00054-0235-24	03/05/2023	0		20	20			10			10	10	10
2 Morphine 15mg Tablet	00054-0235-25	03/05/2023	10		10	10					7	7	13	13
2 Morphine 10mg/mL Injection	00641-6127-25	03/05/2023	6		4	4			4			4	6	6
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	03/05/2023	30		11	11		10	6		2	18	23	23
2 Oxycodone 5mg Tablet	47781-0263-05	03/05/2023	5		6	6		5				5	6	6
2 Oxycodone 5mg Tablet	68084-0354-01	03/05/2023	30		5	5		5	30			35	0	0
2 Oxycodone 5mg Tablet	00406-0552-01	03/05/2023	0		74	74		4	60			64	10	10
2 Oxycodone 5mg Tablet	00406-0552-23	03/05/2023	17		57	57		7	50			57	17	17
2 Oxycodone 5mg Tablet	00904-6966-61	03/05/2023	4								4	4	0	0
2 Oxycodone 10mg Tablet	68084-0968-01	03/05/2023	40		238	238			30			30	248	248
2 Oxycodone 10mg Tablet	65162-0048-10	03/05/2023	32						20			20	12	12
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	03/05/2023	60		10	10			30			30	40	40
2 Oxycodone/Acetaminophen 5/325mg Tablet	47780-0196-01	03/05/2023	24		5	5							29	29
2 Oxycodone/Acetaminophen 5/325mg Tablet	50268-0644-11	03/05/2023	2								2	2	0	0
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	3/5/2023	10										10	10
2 Oxycodone/Acetaminophen 10/325mg Tablet	47781-0230-01	03/05/2023	30		5	5			10		18	28	7	7
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-11	03/05/2023	96		18	18		30	30			60	54	54

Med-Plus Pharmacy Livermore
935 Lindberg Ave, Livermore, CA 94551
DEA # FM2047757
Reconciliation Date: 05/26/2023
Reconciliated by: Michelle (Yulai) Ma

Schedule II Control Substances Inventory Reconciliation Report

					ACQUISITIONS					DISPOSITIONS											
DEA CLASS	ITEM DESCRIPTION	NDC	Date of Last Count	Quantity at Last Count	Total Purchases	MFG Overfill	Total RTS (filled prior to last count)	Total Interpharmacy Transfer-In	Total ADDS/Ext (Reverse Distributor)	Total Acquisitions	Total Dispensed	Total E-68 Usage	ADDS Usage	Total Claim Reversal	Total Interpharmacy Transfer-Out	Reverse Distributor	Damaged	Expired for Reverse Distributor	Total Dispositions	EQUALS: Expected On-hand Quantity	Actual On-hand Count	Variance	Explanation of Variance
2	Dextroamphetamine/Amphetamine 5mg Tablet	00406-8891-01	05/02/2023	193						0									0	193	193		
2	Dextroamphetamine 5mg Tablet	00406-8958-01	05/02/2023	0	100					100	80								80	20	20		
2	Dextroamphetamine/Amphetamine 5mg ER Tablet	66993-0594-02	05/02/2023	76						0									0	76	76		
2	Dextroamphetamine/Amphetamine 10mg ER Tablet	49884-0840-01	05/02/2023	16						0									0	16	16		
2	Dextroamphetamine 10mg Tablet	00555-0953-02	05/02/2023	165						0	35								35	130	130		
2	Dextroamphetamine/Amphetamine 20mg Tablet	00555-0973-02	05/02/2023	12						0									0	12	12		
2	Dextroamphetamine/Amphetamine 15mg ER Capsule	66993-0596-02	05/02/2023	16						0									0	16	16		
2	Dextroamphetamine/Amphetamine 30mg Tablet	13107-0074-01	05/02/2023	86						0									0	86	86		
2	Dextroamphetamine/Amphetamine 20mg ER Tablet	00115-1491-01	05/02/2023	86						0									0	86	86		
2	Hydromorphone 2mg Tablet	00406-3243-01	05/02/2023	1167	600					600	965								965	797	797		
2	Hydromorphone 4mg Tablet	42858-0302-01	05/02/2023	8						0									0	8	8		
2	Hydromorphone 4mg Tablet	00406-3244-01	05/02/2023	433	300					300	530								530	203	203		
2	Hydromorphone 8mg Tablet	42858-0303-01	05/02/2023	7						0									0	7	7		
2	Hydromorphone 8mg Tablet	00406-3249-01	05/02/2023	100						0	12								12	88	88		
2	Hydromorphone 18mg ER Tablet	13811-0703-10	05/02/2023	93						0									0	93	93		
2	Methadone 5mg Tablet	00406-5755-01	05/02/2023	685	500					500	488								488	697	697		
2	Methadone 10mg Tablet	00406-5771-01	05/02/2023	253	1300					1300	888								888	665	665		
2	Methylphenidate 5mg Tablet	16729-0478-01	05/02/2023	190						0									0	190	190		
2	Methylphenidate 10mg Tablet	00406-1144-01	05/02/2023	200						0									60	140	140		
2	Methylphenidate 20mg Tablet	57664-0230-88	05/02/2023	137						0									0	137	137		
2	Methylphenidate 20mg ER Tablet	00406-1473-01	05/02/2023	86						0									0	86	86		
2	Methylphenidate 36mg ER Tablet	31722-0954-01	05/02/2023	93						0									0	93	93		
2	Morphine 10mg ER Capsule	00832-0225-00	05/02/2023	72						0	30								30	42	42		
2	Morphine 15mg ER Tablet	00406-8315-01	05/02/2023	320	400					400	430			28					402	318	318		
2	Morphine 15mg Tablet	00054-0235-25	05/02/2023	295						0	30								30	265	265		
2	Morphine 20mg ER Capsules	00832-0226-00	05/02/2023	142						0									0	142	142		
2	Morphine 30mg Tablet	00054-0236-25	05/02/2023	0	200					200									0	200	200		
2	Morphine 30mg ER Tablet	00406-8330-01	05/02/2023	205	400					400	70								70	535	535		
2	Morphine 30mg ER Capsules	00832-0227-00	05/02/2023	155						0									0	155	155		
2	Morphine 60mg ER Tablet	42858-0803-01	05/02/2023	18						0									0	18	18		
2	Morphine 60mg ER Tablet	00406-8380-01	05/02/2023	88						0	58								58	30	30		
2	Morphine 100mg ER Tablet	42858-0804-01	05/02/2023	267						0									0	267	266	-1	1 tab fell out during RTS. Confirmed with video surviliance
2	Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-01	05/02/2023	1663.5	7000					7000	6002			18			1		6585	2078.5	2078.5		
2	Hydrocodone/Acetaminophen 5/300mg Tablet	42858-0040-01	05/02/2023	80						0	30								30	50	50		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	71930-0020-12	05/02/2023	4						0									0	4	4		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	00406-0124-01	05/02/2023	360	500					500	268			80					238	622	622		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	00406-0124-65	05/02/2023	19						0									0	19	19		
2	Hydrocodone/Acetaminophen 10/325mg Tab	00406-0125-01	05/02/2023	608	2500					2500	2679			154					2525	583	583		
2	Oxycodone 5mg Capsule	62559-0167-01	05/02/2023	122						0									112	10	10		
2	Oxycodone 5mg Tablet	00406-0552-01	05/02/2023	1738	1000					1000	2731						7		2738	0	0		
2	Oxycodone 5mg Tablet	10702-0018-01	05/02/2023	0	6500					6500	4140			90					4050	2450	2450		
2	Oxycodone 10mg Tablet	10702-0056-01	05/02/2023	1060	600					600	1338								1338	322	322		
2	Oxycodone 10mg Tablet	00406-8510-01	05/02/2023	2						0									0	2	2		
2	Oxycodone 10mg Tablet	42858-0002-01	05/02/2023	0	500					500									0	500	500		
2	Oxycodone 15mg Tablet	00406-8515-01	05/02/2023	257	200					200	289								289	168	168		
2	Oxycodone 20mg Tablet	42858-0004-01	05/02/2023	545						0	50								50	495	495		
2	Oxycodone 30mg Tablet	00406-8580-01	05/02/2023	402						0	18								18	384	384		
2	Oxycontin CR 10mg Tablet (Brand)	59011-0410-10	05/02/2023	33	100					100	80								80	53	53		
2	Oxycodone 10mg ER Tablet	69238-2294-01	05/02/2023	200	600					600	256								256	544	544		
2	Oxycontin CR 15mg Tablet (Brand)	59011-0415-10	05/02/2023	127						0									0	127	127		
2	Oxycontin CR 20mg Tablet (Brand)	59001-0420-10	05/02/2023	196						0	88								88	108	108		
2	Oxycodone 20mg ER Tablet	69238-2295-01	05/02/2023	0	300					300	14								14	286	286		
2	Oxycodone 20mg ER Tablet	00093-5732-01	05/02/2023	4						0									0	4	4		
2	Oxycontin 30mg CR Tablet (Brand)	59011-0430-10	05/02/2023	281						0									0	281	281		
2	Oxycontin 40mg CR Tablet (Brand)	59011-0440-10	05/02/2023	100						0									0	100	100		
2	Oxycodone 40mg ER Tablet	69238-2298-01	05/02/2023	200						0									0	200	200		
2	Oxycodone 40mg ER Tablet	00093-5733-01	05/02/2023	26						0									0	26	26		
2	Oxycontin 60mg CR Tablet (Brand)	49011-0460-10	05/02/2023	100						0									0	100	100		
2	Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-01	05/02/2023	841	2000					2000	1234								1234	1607	1607		
2	Oxycodone/Acetaminophen 5/325mg Tablet	42858-0102-01	05/02/2023	7						0									0	7	7		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	47781-0229-01	05/02/2023	52						0	42								42	10	10		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	42858-0103-01	05/02/2023	100						0									0	100	100		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-50	05/02/2023	5						0									0	5	5		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-01	05/02/2023	875	1000					1000	944								944	931	931		
2	Xtampza 9mg ER Capsule	24510-0110-10	05/02/2023	0	100					100	20								20	80	80		
2	Xtampza 13.5mg ER Capsule	24510-0115-10	05/02/2023	23						0									0	23	23		
2	Xtampza 18mg ER Capsule	24510-0120-10	05/02/2023	100						0									0	100	100		
2	Fentanyl 12mcg/hr Patch	00406-9112-76	05/02/2023	1	10					10	9								9	2	2		
2	Fentanyl 12mcg/hr Patch	00378-9119-98	05/02/2023	1	10					10	10								10	1	1		
2	Fentanyl 25mcg/hr Patch	60505-7081-02	05/02/2023	1						0									0	1	1		
2	Fentanyl 25mcg/hr Patch	00378-9121-98	05/02/2023	19						0									0	19	19		
2	Fentanyl 50mcg/hr Patch	00406-9150-76	05/02/2023	3						0	2								2	1	1		
2	Fentanyl 50mcg/hr Patch	00378-9122-93	05/02/2023	3	15					15	17								17	1	1		
2	Fentanyl 75mcg/hr Patch	00378-0812-98	05/02/2023	12						0									0	12	12		
2	Fentanyl 100mcg/hr Patch	00378-9124-98	05/02/2023	15						0									0	15	15		
2	Fentanyl 100mcg/hr Patch	60505-7084-02	05/02/2023	5						0									0	5	5		
2	Hydrocodone/Acetaminophen 7.5/325/15mL Solution	00121-0772-16	05/02/2023	473						0									0	473	473		
2	Hydromorphone 1mg/mL Solution	42858-0304-16	05/02/2023	473						0									0	473	473		
2	Methadone 5mg/5mL Oral Solution	00054-3555-63	05/02/2023	780						0									0	780	780		
2	Methadone 10mg/mL Oral Solution	00527-1927-36	05/02/2023	150	150					150	120								120	180	180		
2	Morphine 100mg/5mL Oral Solution (15ml Package Size)	00054-0517-41	05/02/2023	312						0	143			15					128	184	184		
2	Morphine 100mg/5mL Oral Solution (30ml Package Size)	00406-8003-30	05/02/2023	180						0									0	180	180		
2	Morphine 100mg/5mL Oral Solution (30ml Package Size)	00054-0517-44	05/02/2023	195						0	80								80	115	115		
2	Morphine 10mg/5mL Oral Solution	00054-0237-63	05/02/2023	610						0									0	610	610		
2	Oxycodone 100mg/5mL Oral Solution	71930-0023-30	05/02/2023	30						0									0	30	30		
2	Oxycodone 5mg/5mL Oral Solution	62559-0151-16	05/02/2023	1945						0									0	1945	1945		
2	Hydromorphone 2mg/mL Injection	00409-3365-10	05/02/2023	0						0									0	0	0		
2	Morphine 5mg/10mL Injection	00409-3814-12	05/02/2023	40						0									0	40	40		

2 Morphine 10mg/mL Injection	00641-6127-25	05/02/2023	23								23	23
2 Morphine 4mg/mL Injection	00641-6125-25	05/02/2023	25								25	25
E-Kit Inventory												
2 Hydromorphone 2mg/mL Injection	00409-3365-11	05/02/2023	19								19	19
2 Hydromorphone 2mg Tablet	42858-0301-25	05/02/2023	87				15	40		55	32	32
2 Hydromorphone 2mg Tablet	60687-0579-11	05/02/2023	0		20	20			10	10	10	10
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	05/02/2023	76				10	30		40	36	36
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	05/02/2023	17								17	17
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	05/02/2023	4		31	31	3			3	32	32
2 Morphine 10mg/mL Injection	00641-6127-25	05/02/2023	22								22	22
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	05/02/2023	1								1	1
2 Morphine 15mg Tablet	00054-0235-24	05/02/2023	74								74	74
2 Morphine 15mg Tablet	00054-0235-25	05/02/2023	0		2	2					2	2
2 Oxycodone 5mg Tablet	68084-0354-01	05/02/2023	39				5			5	34	34
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	05/02/2023	70					30		30	40	40
2 Oxycodone/Acetaminophen 5/325mg Tablet	47781-0196-01	05/02/2023	0		10	10					10	10
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	05/02/2023	11				11			11	0	0
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-01	05/02/2023	86				2			2	84	84
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0230-01	05/02/2023	0		5	5			5	5	0	0
CUBEX Inventory												
2 Hydromorphone 2mg Tablet	42855-0301-25	05/02/2023	0		40	40		30		30	10	10
2 Hydromorphone 2mg Tablet	00406-3243-01	05/02/2023	0		3	3					3	3
2 Hydromorphone 2mg Tablet	60687-0579-01	05/02/2023	0		19	19					19	19
2 Hydromorphone 2mg/mL Injection	00409-3365-11	05/02/2023	14		5	5		2		2	17	17
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	05/02/2023	8	100	41	141		40		40	109	109
2 Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-23	05/02/2023	6								6	6
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	05/02/2023	10								10	10
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	05/02/2023	111				31			31	80	80
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	05/02/2023	22								22	22
2 Hydrocodone/Acetaminophen 10/325mg Tab	53746-0110-05	05/02/2023	7								7	7
2 Methadone 5mg Tablet	00406-5755-62	05/02/2023	54								54	54
2 Methadone 10mg Tablet	00054-0710-20	05/02/2023	100								100	100
2 Morphine 15mg Tablet	00054-0235-24	05/02/2023	100								100	100
2 Morphine 15mg Tablet	00054-0235-25	05/02/2023	3								3	3
2 Morphine 10mg/mL Injection	00641-6127-25	05/02/2023	4					2		2	2	2
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	05/02/2023	16		2	2		3		3	15	15
2 Oxycodone 5mg Tablet	47781-0263-05	05/02/2023	6								6	6
2 Oxycodone 5mg Tablet	68084-0354-01	05/02/2023	140		31	31		100		100	71	71
2 Oxycodone 5mg Tablet	00406-0552-01	05/02/2023	30		10	10		30		30	10	10
2 Oxycodone 5mg Tablet	00406-0552-23	05/02/2023	8		9	9		10		10	7	7
2 Oxycodone 10mg Tablet	68084-0968-01	05/02/2023	228		3	3		20		20	211	211
2 Oxycodone 10mg Tablet	65162-0048-10	05/02/2023	4		3	3					7	7
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	05/02/2023	25		33	33		40		40	18	18
2 Oxycodone/Acetaminophen 5/325mg Tablet	47780-0196-01	05/02/2023	0		5	5					5	5
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	5/2/2023	0		15	15		10		10	5	5
2 Oxycodone/Acetaminophen 10/325mg Tablet	47781-0230-01	05/02/2023	12		7	7			7	7	12	12
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-11	05/02/2023	18					10		10	8	8

Med-Pass Pharmacy Livermore
335 Lindbergh Ave, Livermore, CA 94551
DEA # FM2047757
Reconciliation Date: 05/02/2023
Reconciliated by: Michelle (Tube) Ma

Schedule II Control Substances Inventory Reconciliation Report

DEA CLASS	ITEM DESCRIPTION	NDC	Date of Last Count	Quantity at Last Count	ACQUISITIONS: Total Purchases	ACQUISITIONS: MFG Overfill	ACQUISITIONS: Total RTS (filled prior to last count)	ACQUISITIONS: Total Inventory Transfers In	ACQUISITIONS: Total ADDIS/Del Returns	Total Acquisitions	DISPOSITIONS: Total Dispensed	DISPOSITIONS: Total EAA Usage	DISPOSITIONS: ADDS Usage	DISPOSITIONS: Total Claim Reversal	DISPOSITIONS: Total Inventory Transfer Out	DISPOSITIONS: Reverse Distribution	DISPOSITIONS: Damaged	DISPOSITIONS: Returned for Reverse Distributor	Total Dispositions	EQUALS: Expected On Hand Quantity	Actual On Hand Count	Variance	Explanation of Variance
2	Dextroamphetamine/Amphetamine 5mg Tablet	00406-8891-01	04/01/2023	193						0									0	193	193		
2	Dextramphetamine 5mg Tablet	00406-8958-01	04/01/2023	0	100					100	30								30	70	70		
2	Dextroamphetamine/Amphetamine 5mg ER Tablet	66993-0584-02	04/01/2023	76						0									0	76	76		
2	Dextroamphetamine/Amphetamine 10mg ER Tablet	49884-0840-01	04/01/2023	16						0									0	16	16		
2	Dextroamphetamine 10mg Tablet	00555-0953-02	04/01/2023	0	200					200	35								35	165	165		
2	Dextroamphetamine/Amphetamine 20mg Tablet	00555-0973-02	04/01/2023	12						0									0	12	12		
2	Dextroamphetamine/Amphetamine 15mg ER Capsule	66993-0596-02	04/01/2023	16						0									0	16	16		
2	Dextroamphetamine/Amphetamine 30mg Tablet	13107-0078-01	04/01/2023	86						0									0	86	86		
2	Dextroamphetamine/Amphetamine 30mg ER Tablet	00115-1491-01	04/01/2023	86						0									0	86	86		
2	Hydromorphone 2mg Tablet	00406-3243-01	04/01/2023	693	1600					1600	1131								1131	1162	1162		
2	Hydromorphone 4mg Tablet	42858-0302-01	04/01/2023	4						0									0	4	4		
2	Hydromorphone 4mg Tablet	00406-3244-01	04/01/2023	196	500	1				501	264								264	433	433		
2	Hydromorphone 8mg Tablet	42858-0303-01	04/01/2023	7						0									0	7	7		
2	Hydromorphone 8mg Tablet	00406-3249-01	04/01/2023	100						0									0	100	100		
2	Hydromorphone 18mg ER Tablet	13811-0703-10	04/01/2023	93						0									0	93	93		
2	Methadone 5mg Tablet	00054-0709-25	04/01/2023	2						0	2								2	0	0		
2	Methadone 5mg Tablet	00406-5755-01	04/01/2023	846	300					300	461								461	685	684		
2	Methadone 10mg Tablet	00406-5771-01	04/01/2023	243	1100					1100	1090								1090	253	253		
2	Methylphenidate 5mg Tablet	16729-0478-01	04/01/2023	190						0									0	190	190		
2	Methylphenidate 10mg Tablet	10702-0101-01	04/01/2023	26						0	26								26	0	0		
2	Methylphenidate 10mg Tablet	00406-1144-01	04/01/2023	200						0									0	200	200		
2	Methylphenidate 20mg Tablet	57664-0230-88	04/01/2023	137						0										137	137		
2	Methylphenidate 20mg ER Tablet	00406-1478-01	04/01/2023	86						0										86	86		
2	Methylphenidate 36mg ER Tablet	31722-0954-01	04/01/2023	93						0										93	93		
2	Morphine 60mg ER Capsule	00832-0325-00	04/01/2023	138						0	28							33	66	72	72		
2	Morphine 15mg ER Tablet	00406-8315-01	04/01/2023	985						0	683			14					669	320	320		
2	Morphine 15mg Tablet	00054-0235-25	04/01/2023	462						0	166								166	296	295	-1	-1 Medication Error Rx 22023107. Overfilled 1 tablet. Confirmed with video surveillance
2	Morphine 20mg ER Capsules	00832-0226-00	04/01/2023	142						0										141	142		
2	Morphine 30mg Tablet	00054-0236-25	04/01/2023	464						0								464	464	0	0		
2	Morphine 30mg ER Tablet	00406-8330-01	04/01/2023	615						0	430			20					410	205	205		
2	Morphine 30mg ER Capsules	00832-0227-00	04/01/2023	155						0										155	155		
2	Morphine 60mg ER Tablet	42858-0803-01	04/01/2023	18						0										18	18		
2	Morphine 60mg ER Tablet	00406-8380-01	04/01/2023	144						0	56								56	88	88		
2	Morphine 100mg ER Tablet	42858-0804-01	04/01/2023	267						0	7			7					7	267	267		
2	Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-01	04/01/2023	1721	8000					8000	8131			75		1			8057	1664	1663.5	-0.5	-0.5 Manufacturer bottle has a broken tablet. Confirmed bottle discrepancy
2	Hydrocodone/Acetaminophen 5/300mg Tablet	42858-0040-01	04/01/2023	80						0										80	80		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	71930-0020-12	04/01/2023	4						0										4	4		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	00406-0124-01	04/01/2023	98	500					500	218								218	380	380		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab		04/01/2023	19						0										19	19		
2	Hydrocodone/Acetaminophen 10/325mg Tab	00406-0125-01	04/01/2023	666	3600					3600	1684			26					3658	608	608		
2	Oxycodone 5mg Capsule	62559-0167-01	04/01/2023	212						0	90								90	122	122		
2	Oxycodone 5mg Tablet	00406-0552-01	04/01/2023	1364	7000					7000	6626			200					6826	1738	1738		
2	Oxycodone 30mg Tablet	10702-0056-01	04/01/2023	873	1900					1900	1833			120					1713	1060	1060		
2	Oxycodone 10mg Tablet	00406-8510-01	04/01/2023	2						0										2	2		
2	Oxycodone 15mg Tablet	00406-8515-01	04/01/2023	414	500					500	657								657	257	257		
2	Oxycodone 20mg Tablet	00406-8520-01	04/01/2023	28						0	28								28	0	0		
2	Oxycodone 20mg Tablet	42858-0004-01	04/01/2023	305	300					300	60								60	545	545		
2	Oxycodone 30mg Tablet	00406-8540-01	04/01/2023	402						0										402	402		
2	Oxycontin 10mg Tablet (Brand)	59011-0410-10	04/01/2023	193	300					300	460								460	33	33		
2	Oxycodone 10mg ER Tablet	69238-2294-01	04/01/2023	0	200					200										200	200		
2	Oxycontin 15mg Tablet (Brand)	59011-0413-10	04/01/2023	127						0										127	127		
2	Oxycontin CR 20mg Tablet (Brand)	59801-0420-10	04/01/2023	272		20				20	96								96	196	196		
2	Oxycodone 20mg ER Tablet	00093-5732-01	04/01/2023	4						0										4	4		
2	Oxycontin 30mg CR Tablet (Brand)	59011-0430-10	04/01/2023	295						0	14								14	281	281		
2	Oxycontin 40mg CR Tablet (Brand)	59011-0440-10	04/01/2023	100						0										100	100		
2	Oxycodone 40mg ER Tablet	69238-1298-01	04/01/2023	200						0										200	200		
2	Oxycodone 40mg ER Tablet	00093-5733-01	04/01/2023	26						0										26	26		
2	Oxycontin 60mg CR Tablet (Brand)	59011-0460-10	04/01/2023	100						0										100	100		
2	Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-01	04/01/2023	759	1500					1500	1418			4					1414	841	841		
2	Oxycodone/Acetaminophen 5/325mg Tablet	42858-0102-01	04/01/2023	171						0	164								164	7	7		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	47781-0229-01	04/01/2023	94						0	42								42	52	52		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	42858-0103-01	04/01/2023	0	100					100										100	100		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-50	04/01/2023	5						0										5	5		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-01	04/01/2023	760	1000					1000	913			28					885	875	875		
2	Xtampza 13.5mg ER Capsule	24510-0115-10	04/01/2023	23						0										23	23		
2	Xtampza 18mg ER Capsule	24510-0120-10	04/01/2023	100						0										100	100		
2	Fentanyl 12mcg/hr Patch	00406-9112-76	04/01/2023	13						0	12								12	1	1		
2	Fentanyl 12mcg/hr Patch	00378-9119-98	04/01/2023	1						0										1	1		
2	Fentanyl 25mcg/hr Patch	62505-7081-02	04/01/2023	1						0										1	1		
2	Fentanyl 25mcg/hr Patch	00378-9121-98	04/01/2023	19						0										19	19		
2	Fentanyl 50mcg/hr Patch	00406-9150-76	04/01/2023	3						0										3	3		
2	Fentanyl 50mcg/hr Patch	00378-9132-98	04/01/2023	17	15					15	29								29	3	3		
2	Fentanyl 75mcg/hr Patch	00378-0912-98	04/01/2023	12						0										12	12		
2	Fentanyl 100mcg/hr Patch	00378-9124-98	04/01/2023	15						0										15	15		
2	Fentanyl 100mcg/hr Patch	60505-7084-02	04/01/2023	5						0										5	5		
2	Hydrocodone/Acetaminophen 7.5/325/15ml Solution	00121-0772-16	04/01/2023	0	946					946	473								473	473	473		
2	Hydrocodone/Acetaminophen 7.5/325mg/15ml Solution	71930-0027-63	04/01/2023	413						0	425								425	-12	0	12	12 Liquid variation
2	Hydromorphone 1mg/ml Solution	42858-0304-16	04/01/2023	473						0										473	473		
2	Methadone 5mg/5ml Oral Solution	00054-3555-63	04/01/2023	780						0										780	780		
2	Methadone 10mg/ml Oral Solution	00527-1927-36	04/01/2023	150						0						946			946	150	150		
2	Lortab 10/300mg/15ml Oral Solution	17478-0450-16	04/01/2023	946						0										0	0		
2	Morphine 100mg/5ml Oral Solution (15ml Package Size)	00054-0517-41	04/01/2023	290	150					150	138			10					128	312	312		
2	Morphine 100mg/5ml Oral Solution (30ml Package Size)	00406-8003-30	04/01/2023	180						0	30								30	180	180		
2	Morphine 100mg/5ml Oral Solution (60ml Package Size)	00054-0517-44	04/01/2023	225						0	30								30	195	195		
2	Morphine 10mg/5ml Oral Solution	00054-0237-63	04/01/2023	1172						0	600								600	572	616	58	58 Liquid variation/bottle overfill
2	Oxycodone 100mg/5ml Oral Solution	71930-0023-30	04/01/2023	30						0										30	30		
2	Oxycodone 5mg/5ml Oral Solution	62559-0151-16	04/01/2023	1975						0	30								30	2945	2945		
2	Hydromorphone 2mg/ml Injection	00409-3365-10	04/01/2023	10	10					10		10						10	20	0	0		
2	Morphine 5mg/10ml Injection	00409-3814-12	04/01/2023	40						0										40	40		
2	Morphine 10mg/ml Injection	00641-6127-25	04/01/2023	23						0										23	23		
2	Morphine 4mg/ml Injection	00641-6125-25	04/01/2023	25						0										25	25		
	E-Kit Inventory																						
2	Hydromorphone 2mg/ml Injection	00409-3365-11	04/01/2023	8	10					10	20		0					9	9	19	19		

2 Hydromorphone 2mg Tablet	00406-3243-01	04/01/2023			5		13			13	0		
2 Hydromorphone 2mg Tablet	42858-0301-75	04/01/2023		100		100	13			13	87		
2 Hydromorphone 2mg Tablet	60687-0579-11	04/01/2023			31	31			49	49	0		
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	04/01/2023					16			16	76		
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	04/01/2023									17		
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	04/01/2023					19			19	4		
2 Morphine 10mg/mL Injection	00641-6127-25	04/01/2023									22		
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	04/01/2023									1		
2 Morphine 15mg Tablet	00054-0235-24	04/01/2023									74		
2 Morphine 15mg Tablet	00054-0235-25	04/01/2023							6	6	0		
2 Oxycodone 5mg Tablet	02908-6966-61	04/01/2023			4				32	32	0		
2 Oxycodone 5mg Tablet	68084-0354-01	04/01/2023					9	50		59	39		
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-82	04/01/2023									70		
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	04/01/2023					1				11		
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-01	04/01/2023					5				86		
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0230-01	04/01/2023							7	7	0		
CUBEX Inventory													
2 Hydromorphone 2mg Tablet	00406-3243-01	04/01/2023			10	10	20	20		40	0		
2 Hydromorphone 2mg Tablet	60687-0579-01	04/01/2023			2				5	5	0		
2 Hydromorphone 2mg/mL Injection	00409-3365-11	04/01/2023		10		10			2	2	14		
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	04/01/2023			11	11		30		30	8		
2 Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-23	04/01/2023			5			20		20	6		
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	04/01/2023									10		
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	04/01/2023		100	11	11		10		10	111		
2 Hydrocodone/Acetaminophen 10/325mg Tab	00093-6825-61	04/01/2023			7			20		20	22		
2 Hydrocodone/Acetaminophen 10/325mg Tab	53746-0110-05	04/01/2023			3			10		10	7		
2 Methadone 5mg Tablet	00406-5755-62	04/01/2023									54		
2 Methadone 10mg Tablet	00054-0710-20	04/01/2023									100		
2 Morphine 15mg Tablet	00054-0235-24	04/01/2023		100		100		10		10	100		
2 Morphine 15mg Tablet	00054-0235-25	04/01/2023							10	10	3		
2 Morphine 10mg/mL Injection	00641-6127-25	04/01/2023						2			4		
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	04/01/2023			11			18		18	16		
2 Oxycodone 5mg Tablet	47781-0261-05	04/01/2023									6		
2 Oxycodone 5mg Tablet	68084-0354-01	04/01/2023		200	130	130		170		170	140		
2 Oxycodone 5mg Tablet	00406-0552-01	04/01/2023			40	40		20		20	30		
2 Oxycodone 5mg Tablet	00406-0552-23	04/01/2023			11	11		20		20	8		
2 Oxycodone 10mg Tablet	68084-0968-01	04/01/2023						20		20	228		
2 Oxycodone 10mg Tablet	65162-0048-10	04/01/2023			2			10		10	4		
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-82	04/01/2023			5			20		20	25		
2 Oxycodone/Acetaminophen 5/325mg Tablet	47781-0196-01	04/01/2023							29	29	0		
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	4/1/2023						10		10	0		
2 Oxycodone/Acetaminophen 10/325mg Tablet	47781-0230-01	04/01/2023			5						12		
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-11	04/01/2023			4			40		40	18		

Med-Plus Pharmacy Livermore
335 Lindberg Ave, Livermore, CA 94551
DEA # FM2047757
Reconciliation Date: 03/05/2023
Reconciliated by: Michelle (Yuke) Ma

Schedule II Control Substances Inventory Reconciliation Report

DEA CLASS	ITEM DESCRIPTION	NDC	Date of Last Count	Quantity at Last Count	ACQUISITIONS: Total Purchases	ACQUISITIONS: AFG Overfill	ACQUISITIONS: Total RTS (filled prior to last count)	ACQUISITIONS: Total Interpharmacy Transfer-In	ACQUISITIONS: Total CII ADDS/E-kit Returns	ACQUISITIONS: Total Acquisitions	DISPOSITIONS: Total Dispensed	DISPOSITIONS: Total E-kit Usage	DISPOSITIONS: ADDS Usage	DISPOSITIONS: Total Claim Reversal	DISPOSITIONS: Total Interpharmacy Transfer-Out	DISPOSITIONS: Reverse Distributor	DISPOSITIONS: Damaged	DISPOSITIONS: Expired for Reverse Distributor	DISPOSITIONS: Total Dispositions	EQUALS: Expected On-hand Quantity	Actual On-hand Count	Variance	Explanation of Variance
2	Dextroamphetamine/Amphetamine 5mg Tablet	00406-8891-01	01/27/2023	200						0	7								7	193	193		
2	Dextroamphetamine/Amphetamine 5mg ER Tablet	66993-0594-02	01/27/2023	76						0									0	76	76		
2	Dextroamphetamine/Amphetamine 10mg ER Tablet	49884-0840-01	01/27/2023	16						0									0	16	16		
2	Dextroamphetamine 10mg Tablet	00555-0953-02	01/27/2023	155						0	28								28	127	127		
2	Dextroamphetamine/Amphetamine 20mg Tablet	00555-0973-02	01/27/2023	12						0									0	12	12		
2	Dextroamphetamine/Amphetamine 15mg ER Capsule	66993-0596-02	01/27/2023	76						0	60								60	16	16		
2	Dextroamphetamine/Amphetamine 30mg Tablet	13107-0074-01	01/27/2023	86						0									0	86	86		
2	Dextroamphetamine/Amphetamine 30mg ER Tablet	00115-1491-01	01/27/2023	86						0									0	86	86		
2	Hydromorphone 2mg Tablet	42858-0301-01	01/27/2023	736						0	736								736	0	0		
2	Hydromorphone 2mg Tablet	00406-3243-01	01/27/2023	0	1000					1000	434								434	566	566		
2	Hydromorphone 4mg Tablet	42858-0302-01	01/27/2023	380	500					500	516								516	364	364		
2	Hydromorphone 8mg Tablet	42858-0303-01	01/27/2023	119						0	112								112	7	7		
2	Hydromorphone 8mg Tablet	00406-3249-01	01/27/2023	0	100					100									0	100	100		
2	Hydromorphone 16mg ER Tablet	13811-0703-10	01/27/2023	93						0									0	93	93		
2	Methadone 5mg Tablet	00054-0709-25	01/27/2023	665	200					200	589						1		590	275	275		
2	Methadone 5mg Tablet	00406-5755-01	01/27/2023	0	1000					1000	0								0	1000	1000		
2	Methadone 10mg Tablet	00406-5771-01	01/27/2023	374	1500					1500	1050								1050	824	824		
2	Methylphenidate 5mg Tablet	16729-0478-01	01/27/2023	190						0									0	190	190		
2	Methylphenidate 10mg Tablet	10702-0101-01	01/27/2023	100						0									0	100	100		
2	Methylphenidate 20mg Tablet	57664-0230-88	01/27/2023	37	100					100										137	137		
2	Methylphenidate 20mg ER Tablet	00406-1473-01	01/27/2023	86																86	86		
2	Methylphenidate 36mg ER Tablet	31722-0954-01	01/27/2023	93																93	93		
2	Morphine 10mg ER Capsule	00832-0225-00	01/27/2023	138																138	138		
2	Morphine 15mg ER Tablet	00406-8315-01	01/27/2023	179	1300					1300	1308								1308	171	171		
2	Morphine 15mg Tablet	00054-0235-25	01/27/2023	379	200					200	232								232	347	347		
2	Morphine 20mg ER Capsules	00832-0226-00	01/27/2023	0	200					200	58								58	142	142		
2	Morphine 30mg Tablet	00054-0236-25	01/27/2023	464																464	464		
2	Morphine 30mg ER Tablet	00406-8330-01	01/27/2023	544	800					800	577								577	767	767		
2	Morphine 30mg ER Capsules	00832-0227-00	01/27/2023	155																155	155		
2	Morphine 60mg ER Tablet	42858-0803-01	01/27/2023	230							191								191	39	39		
2	Morphine 60mg ER Tablet	00406-8380-01	01/27/2023	0	200					200										200	200		
2	Morphine 100mg ER Tablet	42858-0804-01	01/27/2023	288																288	288		
2	Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-01	01/27/2023	2206	11000					11000	11368			155			1		11214	1992	1992		
2	Hydrocodone/Acetaminophen 5/300mg Tablet	42858-0040-01	01/27/2023	100							20								20	80	80		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	71930-0020-12	01/27/2023	4																4	4		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	00406-0124-01	01/27/2023	4	300					300										304	304		
2	Hydrocodone/Acetaminophen 7.5/325mg Tab	00406-0124-65	01/27/2023	381							362								362	19	19		
2	Hydrocodone/Acetaminophen 10/325mg Tab	00406-0125-01	01/27/2023	1185	5000					5000	5048			30			2		5020	1165	1165		
2	Oxycodone 5mg Capsule	62559-0167-01	01/27/2023	89	200					200	157			120					37	252	252		
2	Oxycodone 5mg Tablet	00406-0552-01	01/27/2023	2580	9000					9000	10664			36					10628	952	952		
2	Oxycodone 10mg Tablet	10702-0056-01	01/27/2023	1192	1500					1500	2293			2			1		2292	400	400		
2	Oxycodone 10mg Tablet	00406-8510-01	01/27/2023	0	1000					1000	582			30					552	448	448		
2	Oxycodone 10mg Tablet	65162-0048-10	01/27/2023	0					30	30	26		4						30	0	0		
2	Oxycodone 15mg Tablet	00406-8515-01	01/27/2023	665							398								398	267	267		
2	Oxycodone 20mg Tablet	42858-0004-01	01/27/2023	127	100					100	148								148	79	79		
2	Oxycodone 30mg Tablet	00406-8580-01	01/27/2023	416																416	416		
2	Oxycontin 10mg Tablet (Brand)	59011-0410-10	01/27/2023	145	300					300	378								378	67	67		
2	Oxycodone 10mg ER Tablet	69238-2294-01	01/27/2023	64							64								64	0	0		
2	Oxycontin 15mg Tablet (Brand)	59011-0415-10	01/27/2023	141																141	141		
2	Oxycontin CR 20mg Tablet (Brand)	59001-0420-10	01/27/2023	0	300					300	84								84	216	216		
2	Oxycodone 20mg ER Tablet	69238-2296-01	01/27/2023	26							26								26	0	0		
2	Oxycodone 20mg ER Tablet	00093-5732-01	01/27/2023	4																4	4		
2	Oxycontin 30mg CR Tablet (Brand)	59011-0430-10	01/27/2023	337																337	337		
2	Oxycontin 40mg CR Tablet (Brand)	59011-0440-10	01/27/2023	100																100	100		
2	Oxycodone 40mg ER Tablet	00093-5733-01	01/27/2023	54																54	54		
2	Oxycontin 60mg CR Tablet (Brand)	49011-0460-10	01/27/2023	100																100	100		
2	Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-01	01/27/2023	861	1000					1000	1527						1		1528	333	333		
2	Oxycodone/Acetaminophen 5/325mg Tablet	42858-0102-01	01/27/2023	300																300	300		
2	Oxycodone/Acetaminophen 7.5/325mg Tablet	47781-0229-01	01/27/2023	265							75								75	190	190		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-50	01/27/2023	1321	500					500	1594			45					1549	272	272		
2	Oxycodone/Acetaminophen 10/325mg Tablet	42858-0104-01	01/27/2023	4																4	4		
2	Xtampza 9mg ER Capsule	24510-0110-10	01/27/2023	72																72	72		
2	Xtampza 13.5mg ER Capsule	24510-0115-10	01/27/2023	23																23	23		
2	Xtampza 18mg ER Capsule	24510-0120-10	01/27/2023	100																100	100		
2	Fentanyl 12mcg/hr Patch	00406-9112-76	01/27/2023	15							8								8	7	7		
2	Fentanyl 12mcg/hr Patch	00378-9119-98	01/27/2023	3							2								2	1	1		
2	Fentanyl 25mcg/hr Patch	00406-9125-76	01/27/2023	7							5								5	2	2		
2	Fentanyl 25mcg/hr Patch	60505-7081-02	01/27/2023	1																1	1		
2	Fentanyl 25mcg/hr Patch	00378-9121-98	01/27/2023	1	5					5										6	6		
2	Fentanyl 50mcg/hr Patch	00406-9150-76	01/27/2023	10							7								7	3	3		
2	Fentanyl 50mcg/hr Patch	00378-9122-98	01/27/2023	15							10								10	5	5		

2 Fentanyl 75mcg/hr Patch	00378-0912-98	01/27/2023	15	15			15		18						18		12		12
2 Fentanyl 75mcg/hr Patch	00505-7083-02	01/27/2023	1						1						1		0		3150
2 Fentanyl 100mcg/hr Patch	00378-9124-98	01/27/2023	15														15		15
2 Fentanyl 100mcg/hr Patch	60505-7084-02	01/27/2023	5														5		5
2 Hydrocodone/Acetaminophen 7.5/325mg/15mL Solution	71930-0027-43	01/27/2023	886														886		886
2 Hydromorphone 1mg/mL Solution	42858-0304-16	01/27/2023	559														559		559
2 Methadone 5mg/5mL Oral Solution	00054-3555-63	01/27/2023	990														990		990
2 Methadone 10mg/mL Oral Solution	00054-3553-44	01/27/2023	23														23		23
2 Methadone 10mg/5mL Oral Solution	00054-3556-63	01/27/2023	500														500		500
2 Lortab 10/300mg/15mL Oral Solution	17478-0450-16	01/27/2023	969												23		946		946
2 Morphine 100mg/5mL Oral Solution (15ml Package Size)	00054-0517-41	01/27/2023	355	225			225		150						150		430		430
2 Morphine 100mg/5mL Oral Solution (30mL Package Size)	00054-0517-44	01/27/2023	360						75						75		285		285
2 Morphine 10mg/5mL Oral Solution	00054-0237-63	01/27/2023	1065						535						535		530		530
2 Oxycodone 100mg/5mL Oral Solution	71930-0023-30	01/27/2023	30														30		30
2 Oxycodone 5mg/5mL Oral Solution	62559-0151-16	01/27/2023	1975														1975		1975
2 Hydromorphone 2mg/mL Injection	00409-3365-10	01/27/2023	20														20		20
2 Morphine 5mg/10mL Injection	00409-3814-12	01/27/2023	40														40		40
2 Morphine 10mg/mL Injection	00641-6127-25	01/27/2023	50														50		50
2 Morphine 4mg/mL Injection	00641-6125-25	01/27/2023	25														25		25
E-Kit Inventory																			
2 Hydromorphone 2mg/mL Injection	00409-3365-11	01/27/2023	9						3						3		6		6
2 Hydromorphone 2mg Tablet	42858-0301-01	01/27/2023	0		6	6			6						6		0		0
2 Hydromorphone 2mg Tablet	60687-0579-11	01/27/2023	45						23						23		22		22
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	01/27/2023	99						44						44		55		55
2 Hydrocodone/Acetaminophen 7.5/325mg Tablet	71930-0020-12	01/27/2023	17														17		17
2 Hydrocodone/Acetaminophen 10/325mg Tab	60687-0418-01	01/27/2023	0	100		100			9						9		91		91
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	01/27/2023	103						11	70				3	84		19		19
2 Morphine 10mg/mL Injection	00641-6127-25	01/27/2023	3						1						1		2		2
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	01/27/2023	22						2					3	5		17		17
2 Morphine 15mg Tablet	00054-0235-24	01/27/2023	67						15						15		52		52
2 Morphine 15mg Tablet	00054-0235-25	01/27/2023	9		8	8											8		8
2 Oxycodone 5mg Tablet	00904-6966-61	01/27/2023	0		7	7											7		7
2 Oxycodone 5mg Tablet	00406-0552-01	01/27/2023	62						32	30					62		0		0
2 Oxycodone 5mg Tablet	68084-0354-01	01/27/2023	0		100	100			32	50					82		18		18
2 Oxycodone 10mg Tablet	68084-0968-01	01/27/2023	200														200		200
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	01/27/2023	0	100		100											100		100
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	01/27/2023	30						13						13		17		17
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-01	01/27/2023	61						35						35		26		26
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0230-01	01/27/2023	0		18	18											18		18
CUBEX Inventory																			
2 Hydromorphone 2mg Tablet	60687-0579-01	01/27/2023	19		10	10				10					10		19		19
2 Hydromorphone 2mg/mL Injection	00409-3365-11	01/27/2023	4		4	4				2					2		6		6
2 Hydrocodone/Acetaminophen 5/325mg Tablet	68084-0895-11	01/27/2023	70		46	46				100					100		16		16
2 Hydrocodone/Acetaminophen 5/325mg Tablet	00406-0123-23	01/27/2023	16		14	14				20					20		10		10
2 Hydrocodone/Acetaminophen 10/325mg Tab	00094-6825-61	01/27/2023	13		103	103				70					70		46		46
2 Hydrocodone/Acetaminophen 10/325mg Tab	53746-0110-05	01/27/2023	11							10					10		1		1
2 Methadone 5mg Tablet	00406-5755-62	01/27/2023	46		8	8											54		54
2 Methadone 10mg Tablet	00054-0710-20	01/27/2023	100														100		100
2 Morphine 15mg Tablet	00054-0235-25	01/27/2023	4		6	6											10		10
2 Morphine 10mg/mL Injection	00641-6127-25	01/27/2023	4		6	6				4					4		6		6
2 Morphine 10mg/0.5mL Oral Syringe	68094-0045-01	01/27/2023	32		10	10				12					12		30		30
2 Oxycodone 5mg Tablet	47781-0263-05	01/27/2023	2		3	3											5		5
2 Oxycodone 5mg Tablet	68084-0354-01	01/27/2023	0		50	50				20					20		30		30
2 Oxycodone 5mg Tablet	00406-0552-23	01/27/2023	7		90	90				80					80		17		17
2 Oxycodone 5mg Tablet	00904-6966-61	01/27/2023	4														4		4
2 Oxycodone 10mg Tablet	68084-0968-01	01/27/2023	0	100	10	110				70					70		40		40
2 Oxycodone 10mg Tablet	65162-0048-10	01/27/2023	30		32	32			30						30		32		32
2 Oxycodone/Acetaminophen 5/325mg Tablet	00406-0512-62	01/27/2023	50		10	10											60		60
2 Oxycodone/Acetaminophen 5/325mg Tablet	47780-0196-01	01/27/2023	9		15	15											24		24
2 Oxycodone/Acetaminophen 5/325mg Tablet	50268-0644-11	01/27/2023	2														2		2
2 Oxycodone/Acetaminophen 5/325mg Tablet	60687-0642-01	1/27/2023	10														10		10
2 Oxycodone/Acetaminophen 10/325mg Tablet	47781-0230-01	01/27/2023	2		28	28											30		30
2 Oxycodone/Acetaminophen 10/325mg Tablet	68084-0710-11	01/27/2023	106							10					10		96		96

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Med-Plus Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 335 Lindberg Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 888-222-8405 Website: www.polarisrx.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: Youhni Middle: Last: Woo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: [redacted] Marble Canyon Pl

City: San Ramon State: CA Zip: 94582

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Oregon State University		09/1997-10/2002	
Address	**City**	**State**	**Zip**
1500 SW jefferson St	Corvallis	OR	97331
Diploma/Degree obtained, if any			
Doctor of Philosophy			
School Name		**From - To (MM/YY – MM/YY)**	
Seoul National University		03/1993-02/1995	
Address	**City**	**State**	**Zip**
1 Gwanak-ro Gwanak-gu	Seoul		
Diploma/Degree obtained, if any			
Master of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Dongduck Women's University		03/1989-02/1993	
Address	**City**	**State**	**Zip**
60 Hwaran-ro 13-gil Sungbook-gu	Seoul		
Diploma/Degree obtained, if any			
Bachelor of pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16-current	[redacted]arble Canyon Pl	San Ramon	CA	94582
From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/07-06/16	[redacted]Rosario Ct	San Ramon	Ca	94583
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			04/16-10/23	
Business Address		**City**	**State**	**Zip**
2995 Ygnacio Valley Blvd		Walnut Creek	CA	94598
Phone	**Title**		**Number of Employed Hours**	
925-256-7230	Pharmacist in Charge		6000+	
Description of Duties				
Overees daily operation of a community pharmacy to ensure it is operated compliant to federal and state regulations in terms of dispensing, distribution, and record keeping related to prescription drugs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Younhi Woo, **certify that as the designated representative for**

Neil Farage,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YW I am at least 21 years of age;
3. YW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Younhi Woo
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/26/2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Younhi Woo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/26/2023

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Alameda

I, Younhi Woo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/28/2023

Date

Subscribed and Sworn to before me this 28th day of Nov. 2023

Notary Public Signature

KHUSHBU P. JAVIYA
COMM. #2413927
Notary Public · California
Alameda County
My Comm. Expires Sep. 20, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Med-Plus Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 335 Lindberg Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 888-222-8405 Website: www.polarisrx.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: Robert Middle: Last: Meyer

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] NW 60th Street

City: Fort Lauderdale State: FL Zip: 33309

Telephone: [redacted] Email: rmeyer@polarisrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Cincinnati			1988 - 1993	
Address		City	State	Zip
2600 Clifton Ave.		Cincinnati	OH	45221
Diploma/Degree obtained, if any				
BS in Accounting, BS in Real Estate				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
	[redacted]North Beach 515	Pompano Beach	FL	33062
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Polaris Pharmacy Services, LLC			2019 - Current
Business Address	**City**	**State**	**Zip**
2900 NW 60th Street	Fort Lauderdale	FL	33309
Phone	**Title**		
954-919-1818	CFO		

Description of Duties

Oversee financial reporting, audit and compliance, planning (budgeting), treasury and capital structure.

Business Name			From - To (MM/YY – MM/YY)
Wellfount Pharmacy			2015 - 2019
Business Address	**City**	**State**	**Zip**
5751 W 73rd St.	Indianapolis	IN	46278
Phone	**Title**		
	CFO and President, LTC Division		

Description of Duties

Direct a team encompassing controllership, business operations, decision support, financial planning and analysis, sales reporting, real estate, business systems, and human resources.

Business Name			From - To (MM/YY – MM/YY)
OrionRX, LLC			2014 - 2015
Business Address	**City**	**State**	**Zip**
13100 Magisterial Dr., Suite 102	Louisville	KY	
Phone	**Title**		
502-213-8444	President & CFO		

Description of Duties

Evaluated area operations to identify opportunities for decreased expenses, implement plans for operational infrastructure of systems, processes, and personnel.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	Minneapolis	Ramsey
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		Minnesota Board of Pharmacy		
Reason/Charge				
Pharmacy was allowing remote order entry				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Please see attached.		Hearing		
Name of Business/Industry/Entity				
Polaris Pharmacy Services if Minnesota, LLC				

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Meyer

Print Name (First, Last)

Robert Meyer

Original Signature (electronic, copies or stamps not accepted)

11/30/23

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Broward

I, IVOR STEWART, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Robert Meyer

Original Signature

11/30/23

Date

Subscribed and Sworn to before me this 30 day of Nov 23.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris, Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Med-Plus Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 335 Lindberg Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address.

City: State: Zip:

Telephone: 888-222-8405 Website: www.polarisrx.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: David Middle: Last: Rombro

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] NW 60th Street

City: Fort Lauderdale State: FL Zip: 33309

Telephone: [redacted] Email: drombro@polarisrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland, Baltimore		05/81	
Address	**City**	**State**	**Zip**
620 W Lexington St.	Baltimore	MD	21201
Diploma/Degree obtained, if any			
B.S of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Baltimore Polytechnic Institute			
Address	**City**	**State**	**Zip**
1400 W Cold Springs Ln	Baltimore	MD	21209
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - Current	[redacted]NW 127 Way	Parkland	FL	33076
06/16 - 09/20	[redacted]NE 28th Terrace	Fort Lauderdale	FL	33309

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Polaris Pharmacy Services, LLC			07/15 - Current	
Business Address		**City**	**State**	**Zip**
2900 NW 60th Street		Fort Lauderdale	FL	33309
Phone	**Title**			
954-919-1818	CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Omnicare Pharmacy			06/08 - 04/14	
Business Address		**City**	**State**	**Zip**
2955 W Corporate Lakes Blvd #600		Weston	FL	33331
Phone	**Title**			
954-660-5555	GM			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	Minneapolis	Ramsey
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		Minnesota Board of Pharmacy		
Reason/Charge				
Pharmacy was allowing remote order entry				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Please see attached.			Hearing	
Name of Business/Industry/Entity				
Polaris Pharmacy Services if Minnesota, LLC				

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Rombro

Print Name (First, Last)

CEO

Original Signature (electronic, copies or stamps not accepted)

12/1/23

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Ivor Stewart, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

CEO

Original Signature

12/1/23

Date

Subscribed and Sworn to before me this 1 day of Dec 2023.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/15/2023	Pending	DE	Wilmington	New Castle County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N23C-02-128		New Castle County Superior Courts		
Reason/Charge				
Breach of contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Polaris Pharmacy Services vs Bonamour Health			Lawsuit	
Name of Business/Industry/Entity				
Polaris Pharmacy Services of Pennsylvania, LLC				

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted)

Date

Docket Report Results

Report Selection Criteria

Case ID: N23C-02-128
Docket Start Date:
Docket Ending Date:

Case Description

Case ID: N23C-02-128 - POLARIS PHARM SERV V BONAMOUR HEALTH
Filing Date: Wednesday, February 15th, 2023
Type: C2 - CCLD: COMPLEX COM LIT DIVISION
Status: CSO - CASE SCHEDULING ORDER

Related Cases

No related cases were found.

Case Event Schedule

Event	Date/Time	Room	Location	Judge
PRE-TRIAL CONFERENCE	27-SEP-2024 10:00 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
JURY SELECTION	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A
TRIAL (CIVIL)	28-OCT-2024 09:30 AM	SCN COURTROOM TBD	SUPERIOR CT NEW CASTLE COUNTY	ADAMS, MEGHAN A

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name

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Docket Report Results

	09:30 AM	COURTROOM TBD	NEW CASTLE COUNTY	

Case Parties

Seq #	Assoc	Party End Date	Type	ID	Name
1	2		PLAINTIFF	@3764760	**POLARIS PHARMACY SERVICES**
Address:	*unavailable*		**Aliases:**	*none*	
2	1		ATTORNEY FOR PLAINTIFF	004356	**FIRTH III, WILLIAM R**
Address:	COHEN SEGLIAS PALLAS GREENHALL 500 DELAWARE AVENUE, SUITE 730 WILMINGTON DE 198010000		**Aliases:**	*none*	
3	7		DEFENDANT	@3764761	**BONAMOUR HEALTH GROUP**
Address:	*unavailable*		**Aliases:**	*none*	
4		09-MAY-2023	JUDGE	004673	**LEGROW, ABIGAIL M**
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		**Aliases:**	*none*	

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Docket Report Results

3	7		DEFENDANT	@3764761	**BONAMOUR HEALTH GROUP**
Address:	*unavailable*		**Aliases:**	*none*	
4		09-MAY-2023	JUDGE	004673	**LEGROW, ABIGAIL M**
Address:	SUPERIOR COURT 500 NORTH KING STREET SUITE 11400 WILMINGTON DE 19801 (302)651-3963		**Aliases:**	*none*	
5			SHERIFF	KCSHRF	**KENT COUNTY, SHERIFF**
Address:	*unavailable*		**Aliases:**	*none*	
6			SHERIFF	NCSHRF	**NEW CASTLE COUNTY, SHERIFF**
Address:	87 READS WAY NEW CASTLE DE 19720		**Aliases:**	*none*	
7	3		ATTORNEY FOR DEFENDANT	003496	**FASIC, G. KEVIN**
Address:	OFFIT KURMAN 222 DELAWARE AVENUE SUITE 1105 WILMINGTON DE 19801		**Aliases:**	FASIC, G KEVIN	
8		10-MAY-2023	JUDGE	TBAJ	**JUDGE, TO BE ASSIGNED**

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	AVENUE SUITE 1105 WILMINGTON DE 19801				
8		10-MAY-2023	JUDGE	TBAJ	**JUDGE, TO BE ASSIGNED**
Address:	*unavailable*		**Aliases:**	*none*	
9			JUDGE	004981	**ADAMS, MEGHAN A**
Address:	SUPERIOR COURT LEONARD L. WILLIAMS JUSTICE CT 500 NORTH KING STREET WILMINGTON DE 19801		**Aliases:**	*none*	

Docket Entries

Filing Date	Description	Name	Monetary
15-FEB-2023 01:26 PM	INIT FILING CCLD	FIRTH III, WILLIAM R	
Entry:	INITIAL FILING CCLD - COMPLEX COMMERCIAL LITIGATION DIVISION DATE DOCKETED: FEBRUARY 18, 2023		
15-FEB-2023 01:26 PM	INITIAL COMPLAINT	FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB		

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Docket Report Results

15-FEB-2023 01:26 PM	INITIAL COMPLAINT		FIRTH III, WILLIAM R	
Entry:	INITIAL COMPLAINT DATE DOCKETED: FEBRUARY 18, 2023 COMPLAINT CASE INFORMATION STATEMENT EXHIBIT A TO COMPLAINT EXHIBIT B TO COMPLAINT EXHIBIT C TO COMPLAINT EXHIBIT D TO COMPLAINT EXHIBIT E TO COMPLAINT EXHIBIT F TO COMPLAINT EXHIBIT G TO COMPLAINT PRAECIPE TO COMPLAINT SUMMONS TO COMPLAINT ACCEPTED BY: JDB TRANSACTION ID: 69155555			
21-FEB-2023 03:32 PM	WRIT ISSUED			
Entry:	WRIT(S) ISSUED ON DATE DOCKETED: FEBRUARY 22, 2023 (1) WRIT ISSUED ON 2-20-23, CHECK #5611 $30.00, TO NEW CASTLE COUNTY SHERIFF ACCEPTED BY: RH TRANSACTION ID: 69188972			
27-FEB-2023 09:16 AM	WRIT RETURN (GENERIC)		NEW CASTLE COUNTY, SHERIFF	
Entry:	WRIT RETURNED: DATE DOCKETED: MARCH 1, 2023 ENTITY - BONAMOUR HEALTH GROUP, LLC. ON 2/22/2023 AT 12:14 PM A COPY OF THE WITHIN WRIT TOGETHER WITH A COPY OF THE SUMMONS AND COMPLAINT WERE SERVED UPON LITIGATION MANAGEMENT REPRESENTATIVE, A REPRESENTATIVE FOR THE REGISTERED AGENT CORPORATION SERVICE COMPANY 251 LITTLE FALLS DRIVE WILMINGTON, DE 19808. ACCEPTED BY: RH TRANSACTION ID: 69223030			
14-MAR-2023 11:55 AM	ANSWER & COUNTERCLAIM		FASIC, G. KEVIN	
Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247			

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Entry:	ANSWER AND COUNTERCLAIM DATE DOCKETED: MARCH 15, 2023 DEFENDANT'S ANSWER WITH COUNTERCLAIMS CERTIFICATE OF SERVICE TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS CASE INFORMATION STATEMENT TO DEFENDANT'S ANSWER WITH COUNTERCLAIMS ENTRY OF APPEARANCE OF G. KEVIN FASIC ON BEHALF OF DEFENDANT ACCEPTED BY: SD TRANSACTION ID: 69336247		
16-MAR-2023 08:28 AM	REFERRED TO CASE SCHEDULING		
Entry:	REFERRED TO CASE SCHEDULING DATE DOCKETED: MARCH 16, 2023		
30-MAR-2023 12:57 PM	ANSWER TO COUNTERCLAIM	FIRTH III, WILLIAM R	
Entry:	ANSWER TO COUNTERCLAIM DATE DOCKETED: MARCH 31, 2023 PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM CERTIFICATE OF SERVICE TO PLAINTIFF'S ANSWER TO DEFENDANT'S COUNTERCLAIM ACCEPTED BY: TNW TRANSACTION ID: 69693405		
11-MAY-2023 01:45 PM	LETTER		
Entry:	LETTER DATE DOCKETED: MAY 12, 2023 THE ABOVE CAPTIONED CASE HAS BEEN REASSIGNED TO JUDGE MEGHAN A ADAMS. PLEASE REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		

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Docket Report Results

Entry:	REMEMBER THAT ON ALL FUTURE DOCUMENTS AND FILINGS ON THIS CASE, COUNSEL MUST REFERENCE THE ASSIGNED JUDGE BY INCLUDING THE JUDGE'S INITIALS (MAA-CCLD) AS A SUFFIX TO THE CIVIL ACTION NUMBER. ACCEPTED BY: TNW TRANSACTION ID: 69996405		
19-MAY-2023 10:13 AM	NOTICE	ADAMS, MEGHAN A	
Entry:	NOTICE DATE DOCKETED: MAY 20, 2023 ORDER SIGNED BY: ADAMS, MEGHAN PER THE EMAIL CORRESPONDENCE BETWEEN CHAMBERS AND COUNSEL ON 5-19-23, A STATUS CONFERENCE WILL BE HELD ON MAY 19TH, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: TRANSACTION ID: 70046520		
19-MAY-2023 02:39 PM	JUDICIAL ACTION FORM		
Entry:	JUDICIAL ACTION FORM DATE DOCKETED: MAY 20, 2023 JUDICIAL ACTION FORM FROM STATUS CONFERENCE HELD ON FRIDAY, MAY 19, 2023 AT 10:45 A.M. VIA ZOOM ACCEPTED BY: SR TRANSACTION ID: 70050068		
06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		
08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE		

Search Home | New Search | Report Selection | Case Description
Related Cases | Event Schedule | Case Parties | Docket Entries

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Docket Report Results

06-JUN-2023 12:23 PM	STIPULATION	FASIC, G. KEVIN	
Entry:	STIPULATION DATE DOCKETED: JUNE 7, 2023 JOINT STIPULATED CASE MANAGEMENT ORDER ACCEPTED BY: SR TRANSACTION ID: 70148008		
08-JUN-2023 07:42 PM	ORDER	ADAMS, MEGHAN A	
Entry:	ORDER DATE DOCKETED: JUNE 10, 2023 ORDER SIGNED BY: ADAMS, MEGHAN GRANTED (JOINT STIPULATED CASE MANAGEMENT ORDER) ADAMS, J. 6-8-23. ACCEPTED BY: SR TRANSACTION ID: 70168936		
29-JUN-2023 10:45 AM	LETTER	FIRTH III, WILLIAM R	
Entry:	LETTER DATE DOCKETED: JUNE 30, 2023 LETTER TO JUDICIAL CASE MANAGER FOR JUDGE ADAMS DATED JUNE 29, 2023 FROM WILLIAM R. FIRTH, III, ESQUIRE RE: NEW ADDRESS AND CONTACT INFORMATION ACCEPTED BY: SR TRANSACTION ID: 70283800		
29-JUN-2023 11:14 AM	NOTICE SRV REQUEST PRODUCTION	FIRTH III, WILLIAM R	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JUNE 30, 2023 NOTICE OF SERVICE OF POLARIS PHARMACY SERVICES OF PENNSYLVANIA, LLC'S FIRST REQUEST FOR PRODUCTION OF DOCUMENTS DIRECTED TO DEFENDANT - SERVED VIA EMAIL ON JUNE 29, 2023 ACCEPTED BY: SR TRANSACTION ID: 70284205		
30-JUN-2023 01:37 PM	NOTICE SRV REQUEST PRODUCTION	FASIC, G. KEVIN	
Entry:	NOTICE OF SERVICE OF REQUEST FOR PRODUCTION DATE DOCKETED: JULY 2, 2023 NOTICE OF SERVICE FOR DEFENDANT'S REQUEST FOR FIRST SET OF INTERROGATORIES AND REQUESTS FOR PRODUCTION OF DOCUMENTS TO PLAINTIFF CERTIFICATE OF SERVICE TO NOTICE OF		

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Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
02/06/2023	Pending	CA	Los Angeles	Los Angeles Country
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23STCV02582		Stanley Mosk Courthouse		
Reason/Charge				
Breach of contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Med-Plus Pharmacy, Inc vs Anaheim Healthcare Center, LLC			Lawsuit	
Name of Business/Industry/Entity				
Med-Plus Pharmacy, Inc.				

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted) Date

CASE INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Case Number: 23STCV02582

MED-PLUS PHARMACY, INC. VS ANAHEIM HEALTHCARE CENTER, LLC, ET AL.

Filing Courthouse: Stanley Mosk Courthouse

Filing Date: 02/06/2023
Case Type: Contract/Warranty Breach - Seller Plaintiff (no fraud/negligence) (General Jurisdiction)
Status: Pending

Click here to access document images for this case

If this link fails, you may go to the Case Document Images site and search using the case number displayed on this page

FUTURE HEARINGS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

01/11/2024 at 09:30 AM in Department 85 at 111 North Hill Street, Los Angeles, CA 90012
Hearing on Application for Writ of Attachment (CCP 484.040)

01/11/2024 at 09:30 AM in Department 85 at 111 North Hill Street, Los Angeles, CA 90012
Hearing on Application for Writ of Attachment (CCP 484.040)

06/24/2024 at 08:30 AM in Department 39 at 111 North Hill Street, Los Angeles, CA 90012
Post-Mediation Status Conference

10/18/2024 at 09:30 AM in Department 39 at 111 North Hill Street, Los Angeles, CA 90012
Final Status Conference

10/29/2024 at 09:30 AM in Department 39 at 111 North Hill Street, Los Angeles, CA 90012
Jury Trial

PARTY INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
A - P R - W

ANAHEIM HEALTHCARE CENTER LLC DBA ANAHEIM HEALTHCARE CENTER - Defendant

BARTLETT CARE CENTER LLC DBA FRENCH PARK CARE CENTER - Defendant

BERGMAN ROBERT DAVID - Attorney for Plaintiff

BRUCKER GARY KEITH - Attorney for Defendant

CITRUS NURSING CENTER DBA CITRUS NURSING CENTER - Defendant

COLLEGE VISTA LLC DBA COLLEGE VISTA CARE CENTER - Defendant

COMMUNITY CARE REHAB CENTER LLC DBA COMMUNITY CARE REHABILITATION CENTER - Defendant

COUNTRY OAKS PARTNERS LLC DBA COUNTRY OAKS CARE CENTER - Defendant

DOES 1-20 - Defendant

F. & B. HEALTHCARE DBA EXTENDED CARE HOSPITAL OF RIVERSIDE - Defendant

GARDEN PARK CARE CENTER LLC DBA GARDEN PARK CARE CENTER - Defendant

GIBRALTAR CONVALESCENT HOSPITAL INC. DBA DEL MAR CONVALESCENT HOSPITAL DBA SUNSET MANOR CONVALESCENT HOSPITAL - Defendant

GORDON LANE HEALTHCARE LLC DBA GORDON LANE CARE CENTER - Defendant

HERITAGE MANOR HEALTHCARE LLC DBA HERITAGE MANOR HEALTHCARE - Defendant

INLAND MEDICAL ENTERPRISES INC. DBA ALCOTT REHABILITATION HOSPITAL - Defendant

MED-PLUS PHARMACY INC. DBA MED-PLUS PHARMACY LTC - Plaintiff

MJB PARTNERS LLC DBA POMONA VISTA CARE CENTER - Defendant

MONTERREY PARK CONVALESCENT HOSPITAL INC. DBA MONTERREY PARK CONVALESCENT HOSPITAL - Defendant

PARAMOUNT CONVALESCENT GROUP INC. DBA PARAMOUNT CONVALESCENT HOSPITAL - Defendant

PARK REGENCY CARE LLC DBA PARK REGENCY CARE CENTER - Defendant

PC CARE LLC DBA PACIFIC CONVALESCENT CENTER - Defendant

PUENTE PARTNERS LLC DBA VICTORIA CARE CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

RIVERSIDE EQUITIES LLC DBA MISSION CARE CENTER - Defendant

SIERRA VIEW CARE HOLDINGS LLC DBA SIERRA VIEW CARE CENTER - Defendant

SUN MAR HEALTHCARE INC. DBA SUN-MAR NURSING CENTER - Defendant

VILLA RANCHO BERNARDO HEALTH CARE LLC DBA VILLA RANCHO BERNARDO CARE CENTER - Defendant

WYNGATE NURSING CENTER DBA NORTH VALLEY NURSING CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

DOCUMENTS FILED

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Documents Filed (Filing dates listed in descending order)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail

Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

07/27/2023 Notice of Ruling
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

07/14/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 07/14/2023)
Filed by Clerk

07/14/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

06/29/2023 Decision on Applications for Right to Attach Orders
Filed by Clerk

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/29/2023 Minute Order ((Hearing on Application for Writ of Attachment against (1) Def...))
Filed by Clerk

06/27/2023 Objection (to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/27/2023 Reply (Brief ISO Application for Right to Attach Order)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/22/2023 Declaration (Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Objection (Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Opposition (To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities

Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

05/31/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 05/31/2023)
Filed by Clerk

05/31/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

05/24/2023 Case Management Statement
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/23/2023 Case Management Statement
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

05/19/2023 Minute Order ((Hearing on Ex Parte Application of Plaintiff for Temporary Pr...))
Filed by Clerk

05/18/2023 Opposition (Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr.)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/18/2023 Declaration (of Richard Fond re Ex Parte for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Declaration (In support of Temporary Protective Order)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Ex Parte Application (for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

03/30/2023 Answer
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

03/01/2023 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

02/15/2023 Notice (of Case Management Conference)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

02/10/2023 Notice of Case Management Conference
Filed by Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case
Filed by Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet
Filed by Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing
Filed by Clerk

02/06/2023 Alternate Dispute Resolution Packet
Filed by Clerk

02/06/2023 Summons (on Complaint)
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

02/06/2023 Civil Case Cover Sheet
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

02/06/2023 Complaint
Filed by MED-PLUS PHARMACY, INC. (Plaintiff)

PROCEEDINGS HELD

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Proceedings Held (Proceeding dates listed in descending order)

07/26/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Vacated**

07/14/2023 at 3:41 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

06/29/2023 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Denied**

06/08/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Continued - by Court**

05/31/2023 at 2:34 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

05/19/2023 at 08:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Ex Parte Application (In support of Temporary Protective Order) - **Held - Motion Denied**

REGISTER OF ACTIONS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

07/27/2023 Notice of Ruling; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

07/14/2023 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Minute Order (Non-Appearance Case Review)

07/14/2023 Certificate of Mailing for (Non-Appearance Case Review) of 07/14/2023; Filed by: Clerk

07/14/2023 On the Court's own motion, Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Vacated on 07/14/2023

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/29/2023 Decision on Applications for Right to Attach Orders; Filed by: Clerk

06/29/2023 Minute Order (Hearing on Application for Writ of Attachment against (1) Def...)

06/29/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 06/29/2023; Result Type to Held - Motion Denied

06/27/2023 Reply Brief ISO Application for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/27/2023 Objection to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/22/2023 Opposition To Plaintiffs Application For Right To Attach Orders Against Defendants,Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Objection Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC

(Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85

05/31/2023 Minute Order (Non-Appearance Case Review)

05/31/2023 Certificate of Mailing for (Non-Appearance Case Review) of 05/31/2023; Filed by: Clerk

05/31/2023 Updated -- Gary Keith Brucker (Attorney): Organization Name: Lewis Brisbois Bisgaard & Smith LLP; Middle Name changed from K. to Keith

05/31/2023 Address for Gary Keith Brucker (Attorney) null

05/31/2023 On the Court's own motion, Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Continued - by Court was rescheduled to 07/26/2023 08:30 AM

05/24/2023 Case Management Statement; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant)

05/23/2023 Case Management Statement; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Name Extension changed from In support of Temporary Protective Order to for Temporary Protective Order ; As To Parties changed from ANAHEIM HEALTHCARE CENTER, LLC (Defendant) to ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Denied ; Result Date: 05/19/2023

05/19/2023 Minute Order (Hearing on Ex Parte Application of Plaintiff for Temporary Pr...)

05/19/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 05/19/2023; Result Type to Held - Motion Denied

05/18/2023 Ex Parte Application In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/18/2023 Declaration In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Declaration of Richard Fond re Ex Parte for Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC.

(Plaintiff)

05/18/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85

05/18/2023 Opposition Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr. Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LL

03/30/2023 Answer; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant); As to: MED-PLUS PHARMACY, INC. (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

03/01/2023 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/15/2023 Notice of Case Management Conference; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/10/2023 Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Address for Robert David Bergman (Attorney) updated

02/10/2023 Notice of Case Management Conference; Filed by: Clerk

02/07/2023 Case assigned to Hon. Stephen I. Goorvitch in Department 39 Stanley Mosk Courthouse

02/06/2023 Complaint; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Civil Case Cover Sheet; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Summons on Complaint; Issued and Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Alternate Dispute Resolution Packet; Filed by: Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing; Filed by: Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet; Filed by: Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case; Filed by: Clerk

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Med-Plus Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 335 Lindberg Ave

City: Livermore State: CA Zip: 94551

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 888-222-8405 Website: www.polarisrx.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: Steven Middle: Randall Last: Baker

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] NW 60th Street

City: Fort Lauderdale State: FL Zip: 33309

Telephone: [redacted] Email: sbaker@polarisrx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
VCU School of Pharmacy		08/89 - 06/92	
Address	**City**	**State**	**Zip**
410 North 12th Street	Richmond	VA	23298
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Southwest Virginia Community College		08/87 - 06/89	
Address	**City**	**State**	**Zip**
635 Community College Road	Cedar Bluff	VA	24609
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
Richlands High School		08/83 - 06/87	
Address	**City**	**State**	**Zip**
138 Tornado Alley	Richlands	VA	28574
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - Current	[redacted]N Ocean Boulevard, Unit 1707	Pompano Beach	FL	33062
02/20 - 02/22	[redacted] SE 2nd Ave., Unit 416	Delray Beach	FL	33443
02/19 - 02/20	[redacted]NE 5th St., Unit 214	Delray Beach	FL	33483
02/18 - 02/19	[redacted]W Camino Real	Boca Raton	FL	33486
02/16 - 02/18	[redacted]Port Royale Dr. S	Fort Lauderdale	FL	33308
02/14 - 02/16	[redacted] SE 5th Ave.	Fort Lauderdale	FL	33301
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Polaris Pharmacy Services, LLC			11/2015 - Current
Business Address	**City**	**State**	**Zip**
2900 NW 60th Street	Fort Lauderdale	FL	33309
Phone	**Title**		
954-919-1818	Chief Operating Officer		
Description of Duties			
Oversee day-to-day operations of pharmacy and customer retention.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	Minneapolis	Ramsey
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
265679		Minnesota Board of Pharmacy		
Reason/Charge				
Pharmacy was allowing remote order entry				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Please see attached			Hearing	
Name of Business/Industry/Entity				
Polaris Pharmacy Services of Minnesota, LLC				

Provide explanation below:

Please see attached.

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Steven Baker

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/29/2023

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Broward

I, IVOR STEWART, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/29/2023

Date

Subscribed and Sworn to before me this 29 day of Nov 23.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris, Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☒ Service Modification* ☒ Name Change* (if only a Name Change occurred, submit a **$50.00 fee with** the application.) * Current license #: PH 04544	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Closed-door, long term care pharmacy	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FM2048090 ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☒ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: POLARIS PHARMACY SERVICES

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): Same as mailing address

City: _____ State: _____ Zip: _____

Telephone: 866-463-3757 Toll Free # (NAC 639.708, NRS 639.23286): 866-463-3757

Fax: 877-363-3757 Contact Email: ghunt@polarisrx.com

Website: www.polarisrx.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Albert Won

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19452

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Albert Won	NV Pharmacist Registration #: 19452
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Polaris Pharmacy Services of California, LLC

Corporation/Organization Name: Med-Plus Pharmacy, LLC

Mailing Address: 2900 NW 60th Street

City: Fort Lauderdale State: FL Zip: 33309

Telephone: 866-463-3757 Email: ghunt@polarisrx.com

Contact Person Name: Gina Hunt

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Med-Plus Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

David W. Rombro

Print Name of Authorized Person

CEO

Original signature of Authorized Person (copies or stamps not accepted)

1/18/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Rombro

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

CEO

Original signature of Authorized Person (copies or stamps not accepted)

1/18/24

Date

Board Use Only	Date Received: _____ Amount: _____

MedPlus Pharmacy, LLC DBA Polaris Pharmacy Services

760 Arrow Grand Circle
Covina, CA 91722

Phone: (866) 463-3757
FEIN: 06-1643725
State Rx Lic: PHY58706

Officers

David Rombro (CEO)
[redacted]NW 127 Way
Parkland, FL 33076
Phone: (800) 589-9747
Email: drombro@polarisrx.com

Robert Meyer (CFO)
[redacted]North Ocean 515
Pompano Beach, FL 33062
Phone: (800) 589-9747
Email: rmeyer@polarisrx.com

Steven Baker (COO)
[redacted]Bayshore Drive, Unit 803
Fort Lauderdale, FL 33304
Phone: (800) 589-9747
Email: sbaker@polarisrx.com

Ownership

Polaris Pharmacy Services

- Owned by: Med-Plus Pharmacy, LLC
    - *which is owned by*: Polaris Pharmacy Services of Los Angeles, LLC (100%)
        - *which is owned by*: Polaris Pharmacy Services of California, LLC (100%)
            - *which is Owned by*: Polaris Pharmacy Services, LLC (100%)

***all have same officers**

Polaris Pharmacy Services, LLC
2900 NW 60th Street
Fort Lauderdale, FL 33309

FEIN:	47-4098540
Owned by:	Da Pharmacy Guys, LLC (22.03%) Enhanced Medical Services (24.30) EJJ Pharma, LLC (24.30%) PPGRX North Carolina, LLC (29.37%)
Managers:	David W. Rombro, Daniel Galbut, Harold Sussman
Officers:	David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

Managers

David Rombro
[redacted]NW 127 Way
Parkland, FL 33076
Phone: [redacted]
Email: [redacted]

Daniel Galbut
[redacted]49th Avenue
Hollywood, FL 33021
Phone: [redacted]
Email: [redacted]

Harold Sussman
[redacted]Avenue L
Brooklyn, NY 11230
Phone: [redacted]
Email: [redacted]

Owners 5% or More

Name	DOB	SSN	% of Ownership
David Rombro [redacted]NW 127 Way Parkland, FL 33076	[redacted]		8.57%

Steve Baker [redacted] 7.34%
[redacted]Bayshore Drive, Unit 803
Fort Lauderdale, FL 33304

Todd Zisek [redacted] 6.12%
[redacted]French Lace Drive
Lutz, FL 33558

Jonathan Paritzky [redacted] 8.52%
[redacted]Andover Lane
Woodmere, NY 11598

Eric Galbut [redacted] 5.38%
[redacted]N. Jefferson Avenue
Miami Beach, FL 33140

Daniel Galbut [redacted] 5.38%
[redacted]N. 49th Avenue
Hollywood, FL 33021

Naftali Zanziper [redacted] 7.34%
[redacted]Ave N.
Brooklyn, NY 11210

Simcha Hyman [redacted] 7.34%
[redacted]Wesley Chapel Road
Suffers, NY 10901

Responsible agent for Board Communication

Gina Hunt
ghunt@polarisrx.com
[redacted]NW 60th Street
Fort Lauderdale, FL 33

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	MED-PLUS PHARMACY, LLC
Entity No.:	2480380
Registration Date:	08/09/2002
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 02, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 170091421

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Please provide the following to Inspector Patell at suzy.patell@dca.ca.gov, no later than 6/24/2023:
1. Plan of compliance with accurate documentation of the date a CSP is compounded on each compounding record.
2. Changes made to practice of minibag plus adapter, bag and vial dispensing to comply with labeling, prescription orders. Please provide an example to illustrate.
3. Revised P&Ps for: BUD determination; Quality assurance for end product testing; Recalls; ADRs: actions when viable sampling levels are exceeded.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Flynn Lew

Pharmacist (print) Flynn Lew

Inspector (sign) Suzy Patell

Inspector (print) SUZY PATELL

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 6/19/2023 Inspector: Suzy Patell

Firm: MED-PLUS PHARMACY Phone: (866) 463-3757

Address: 760 ARROW GRAND CIR City: COVINA Zip: 91772

Ownership: CORPORATION

Permit #: LSC101776 PHY58706 Permit Exp: 8/1/2023 DEA#: FM2048090 DEA Exp: 1/31/2025

Date of Self Assessment Form: 9/7/2022 Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 24Hr Hours Saturday 24Hr Hours Sunday: 24Hr

PIC FLYNN H LEW RPH37120 Administrator

RPH Consultant

Staff RPH Name:	License #:
STANLEY W GOLDENBERG	RPH25720
ALBERT C WON	RPH75811
ANNA M CHAN	RPH65792
AUDREY T SHING	RPH52382
CELESTE HA	RPH54688
CHARISSA C ONG	RPH78246
EVA F MAGBUHOS	RPH74323
JOHN S DIBBINI	RPH83778
MAHA A ELSERAFI	RPH81389
LYNNA LE	RPH85324
MALLERY T SY	RPH74237
OFELIA R RENTORIA	RPH45104
PETER H HANNA	RPH81583
SAMEH LOTFY ABD S KHALI	RPH66921
TAMER F DIMIAN	RPH58134
TIFFANY L NGUYEN	RPH58015
DINA A MUSTAFA	INT45038
SARA N ALTOWAIJI	INT44984

Staff Name:	License #:
AILEEN T FUKASAWA	TCH90094
ALANEE A PINEDO	TCH188209
AMBER T VARGAS	TCH50828
ANDREA N ENRIGHT	TCH136603
BINH LE	TCH55217
BRIANA J SANCHEZ	TCH153600
CHRISTINE MARIE P CONNOR	TCH154641
CHUONG H LUONG	TCH59837
DEJANE R QUINTANA	TCH171335
DIANA D PINEDO	TCH187963
EDGAR F GARCIA	TCH40169
EDGARDO SANCHEZ GAONA	TCH113910
FERDINAND S BUNDA	TCH27820
GEMMA B LAGASCA	TCH14700
GIOVANNI REYES	TCH183634
HERIBERTO M MEJIA	TCH54638
INGRID A CONTRERAS	TCH133688
JAMIE WALDIE	TCH39470
JASMINE M PRICE	TCH33031
JEANETTE D LAW	TCH145314
JEANETTE M FLIEHLER	TCH165126
JONATHAN CRUZ	TCH77184
JOSELITO V RECINTO	TCH60516
JOSEPH V DEL VALLE	TCH9066

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INSPECTION REPORT

JUAN C CUCAL	TCH148143
KELLY Y TRIGUEROS	TCH95121
KEVIN CONTRERAS	TCH93207
MABEL A RODRIGUEZ	TCH178095
MARIA M GALLEGOS	TCH34726
MARIA T CONTRERAS	TCH8517
MARICELLA A VILLASENOR	TCH183435
MARTHA MEDINA-CONTRER	TCH49290
MARTIN I CHOW	TCH89903
NATHAN L RAMIREZ	TCH140701
NEOLANNLA WOODS	TCH175262
NORMAN J NICHOLS	TCH108505
RALPH M GOMEZ	TCH126129
RAVEN A SANCHEZ	TCH143860
RAYMOND E SOTO	TCH96385
REBECCA A MONTENEGRO	TCH178888
REZZIE C MEDALLA	TCH133888
RICARDO OLIVA	TCH143056
ROBERT P LUCERO	TCH146879
RUDOLPH P ORTIZ	TCH42820
RUFINA M BANZUELA	TCH6375
RUTH TEZAGUIC PEREZ	TCH180666
SCOTT E HARRISON	TCH20027
SHANNEE E GOODWIN	TCH143902
STACY A MAYEDA	TCH14920
SUSIE G PEREZ	TCH14250
TERESITA G DE JESUS	TCH2786
THAIS ROMERO-VARELA	TCH179013
VICTOR E ROMERO	TCH20420
VILMA D SANTELLAN	TCH48830
VIRGINIA BRACAMONTES RI	TCH180939
YANCY V UY	TCH29063
YASMIN MENDOZA	TCH171500

Inspector Remarks:

Closed door outpatient pharmacy located in a business park, servicing about 200 SNFs. CSPs compounded in a prefabricated structure within pharmacy warehouse area. Inspection conducted with PIC Flynn Lew, RPH Audrey Shing and TCH Gemma Lagasca. Per PIC, about 2 CSPs compounded daily. Practice of providing unspiked piggy bags, minibag plus devices, and antibiotic vials and the labeling thereof, discussed with PIC and education provided for labeling each ingredient supplied with appropriate instructions for mixing, pursuant to a matching prescription for the unmixed ingredients rather than for the admixed IVPB. PIC to communicate a plan after review.
PIC Name and contact: Flynn Lew <flynn.lew@medpluslic.com> 866-463-3757 x1999
ADRs/**Waivers:** none per PIC

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INSPECTION REPORT

Documents reviewed: 6/14-6/16/2023
Date of Inspection: 6/19/2023

LSC RENEWAL INSPECTION:
Compounding Area: ISO 8 positive pressure anteroom with clean/dirty sides, sink, eyewash, garbing, rack and cleaning supplies, leads to a positive pressure ISO 7 non-HD buffer room with carts, an ISO 5 LFW and a passthrough window with interlocking door connecting to the non-ISO classified pharmacy. Per PIC, the pass through is cleaned, but never used. Advised labeling the pass through as non-usable, to ensure compliance with PIC's instructions, by all pharmacy staff.
Certification/Smoke pattern video: via CRS 2/2/2023. Smoke video of PEC provided to view.
Environmental viable sampling: viable volumetric air and surface sampling in all ISO classified areas, via CRS- last 2/2/2023. In-house surface sampling in PEC available and reviewed with RPH Shing. Discussed compliance with upcoming USP 797, effective 11/1/2023.
Hazardous Drugs Compounding: none, per PIC.
Record Keeping Requirements:

- Master Formula: in table format. Reviewed for ertapenem and discussed BUDs based on stability, sterility
- Compounding Worksheets: reviewed for ertapenem, micafungin. Date prepared and Rx date are inaccurate. Documentation of quality reviews and post compounding steps by RPH unavailable. PIC to review and provide plan of compliance with documentation of reviews, steps and date compounded on compounding log.
- Label: date compounded; 'compounded by' notification; storage: available on CSPs. Label for ceftriaxone dispensed as separate vials, bags and minibag plus adapters but labeled with instructions for infusion, and not instructions for mixing. Rx order is for admixed ceftriaxone, per PIC. Please review and advise on changes to be made to practice, labeling, prescription orders.
- Cleaning Documentation: daily, weekly, monthly cleaning logs reviewed- use of PeriDox monthly and PeriDox/PreEmpt daily in weekly alternating cycles noted.
- Refrigerator/Freezer/Room/Incubator Temp., Pressure: Excel logs available. Continuous monitoring w/notification via GoVee, and audible alarm for pressure available in 24 hour pharmacy.
- Training: written, video, gloved finger tip sampling, medium risk media fill, observational validation provided for RPH Tiffany Nguyen was reviewed and lack of observational validation of demonstrated daily, weekly, monthly cleaning tasks pointed out to PIC. Please remedy for all compounding staff and their supervising RPHs.

Protective Clothing: observed during inspection and reviewed in training
Policy and Procedures: PIC tasked with review and revision based on current practice and current regulations.

- Actions when viable sampling levels are exceeded: Please review as discussed
- Training of staff: Please revise based on gaps in administered competencies for RPH Nguyen.
- Hand hygiene and garbing: available
- Cleaning of Facilities/Equipment: spot checked.
- Annual review by PIC: completed 6/14/2023, per PIC. Education provided on reviewing P&Ps against regulations and practice to gauge compliance with the stricter standards.
- Recall of compounded drugs; ADRs: available. Please review and revise for definition of ADRs, recall of CSPs compounded by pharmacy which fall below minimum standards of integrity potency, quality and labeled strength, and for notification to Board.
- Documentation used to determine BUD: Please revise to current strictest standards.
- Qualitative/Quantitative Analysis/frequency: Policy requires testing annually. PIC educated on current standards requiring more than one qualitative and quantitative analysis per year. Please revise. Practice is to send 2 CSPs annually (twice a year) for potency, sterility and endotoxin testing- results from January and May 2023 from ARL available for review.

Education: New USP 797, 800 enforceable 11/1/2023 for facility requirements, viable sampling, activities considered as compounding

DISCUSSION:

Compound Worksheet

3256

MICHAEL FOX THE HILLS POST ACUTE(19) ROOM # A128B PAGE: 1

RX NUMBER : 09448141
DRUG DISP : IV-MICAFUNGIN 150MG/100
PHARMACIST: SHING, AUDREY
DOCTOR : R. SCHREIMAN
ALLERGIES : LITHIUM
Prepared : 03/31/23 By:RPh:AS Tech:

RX DATE : 06/21/23
QTY DISPENSED: 1
HEIGHT :
WEIGHT : .00 lbs
Compound Lot# 9448141 62123

Compound Name.. IV-MICAFUNGIN 150MG/100

3 pm

Drug NDC	Description	Amount/Conc	M/U	Lot Number	Filler Init	Checker Init
1) 71288-0028-11	MICAFUNGIN 50 MG VIAL	3	VIA	K3E010 SAY		3
Manufacturer: MEITHEAL PHARMA						
Expiration Date: 9-24						
2) 00338-0049-18	SOD CHLORIDE 0.9% INJ(EXC)	100	ML	P442073		1
Manufacturer: BAXTER HEALTHCA						
Expiration Date: 10-24						
3) 00338-0049-18	SOD CHLORIDE 0.9% INJ(EXC)	15	ML	P442073		4
Manufacturer: BAXTER HEALTHCA						
Expiration Date: 10-24						

Line headings are imbedded in the QS1 operating system; Ticket opened with QS1 to request the word "Prepared" changed to "Original" instead.

QS1 terminology:
Prepared date: order entry date of initial order
RX date: actual fill date

Information

Type: Compound
Group:

Total Amount: 118
Label Quantity:
Label Unit: BAG
Expiration Days: 1
Use By: 06/22/23

Category 1: IV
Category 2: IVG
Category 3:
Category 4:
Category 5:
Category 6:

Notes:
DOSE: 15ML=150MG

EQUIPMENT:ISO 7 IV CLEAN ROOM,ISO 5 IV HOOD

SUPPLIES:10 ML SYRINGE,NEEDLE, ALCOHOL SWAB

CLEAN ROOM GEAR: BOUFFANT CAP, MASK, GOWN, STERILE GLOVES, SHOE COVERS

PROCEDURES:

COMPLETE IV COMPOUNDING RECORD SHEET. PHARMACIST TO VERIFY DOSE AND CALCULATIONS. INSPECT VIALS AND SUPPLIES ARE FREE OF PARTICLE AND DISCOLORATION.WIPE RUBBER TOPS WITH ALCOHOL. RECONSTIUTE 3 VIALS OF 50MG MYCAFUNGIN WITH 5ML NORMAL SALINE TO EACH VIAL. TO MINIMIZE FOAMING, GENTLY SWIRL TO DISSOLVE; DO NOT SHAKE. THEN WITHDRAW AND ADD FULL CONTENT INTO 100ML NS BAG. WHEN USED IN CHILDREN THE FINAL CONCENTRATION SHOULD BE BETWEEN 0.5-4MG/ML; CONCENTRATION >1.5MG/ML SHOULD BE ADMINISTERED VIA CENTRAL CATHETER.

9448141 62123

MP MED-PLUS PHARMACY LTC
760 ARROW GRAND CIRCLE
COVINA, CA 91722
866-463-3757
MEITHEAL PHARMA
Qty: 1 BAG/ 1.0000 REFILL
THE HILLS POST ACUTE(19)
Prescriber: R. SCHREIMAN A128B
THP
Ins: THP IV 0722 RF: 03
RX # 9448141
IV-MICAFUNGIN 150MG/100
FOX, MICHAEL
Discard After: 06/22/23
Batch Number:
RECORDER
THP

RX # 9448141 06/21/23
FOX, MICHAEL
IV-MICAFUNGIN 150MG/100

INFUSE 150MG (100ML)
IVPBOVER 60MINS (100ML/HR)
EVERY 24HRS UNTIL 7/20/23
*PROTECT FROM LIGHT FOR
STORAGE & DURING INFUSION*
DO NOT REFRIGERATE*

NDC# 71288-0028-11 RPh: AS Tech:

Compound Worksheet

MICHAEL FOX PAGE: 2

RX NUMBER: 09448141 RX DATE: 06/21/23 DRUG DISP: IV-MICAFUNGIN 150MG/100

INSPECT FINAL COMPOUNDED SOLUTION FOR ANY PRECIPITATION AND ABNORMAL DISCOLORATION. PROTECT INFUSION SOLUTION FROM LIGHT (IT IS NOT NECESSARY TO PROTECT THE DRIP CHAMBER OR TUGING FROM LIGHT). PHARMACIST TO PERFORM FINAL REVIEW AND QUALITY CHECK OF FINAL PRODUCT.

STORAGE AND STABILITY: ROOM TEMPERATURE DISCARD AFTER 1 DAY

REFERENCE:

USP CHAPTER 797,2019

LEXICOMP

STERILE COMPOUNDING AND ASEPTIC TECHNIQUE: CONCEPTS, TRAINING AND ASSESSMENT FOR PHARMACY TECHNICIANS

PACKAGE INSERT

RPH _____ DATE 6/21/23

Administration information

Route: 47625008 Date/Time Tracking: N Authorized:

Compound Worksheet

CRAIG PATERSON FRIENDSHIP MANOR NURSING(ROOM # 2019B PAGE: 1
RX NUMBER : 09448527
DRUG DISP : IV-DAPTOMYCIN 850MG/50NS
PHARMACIST: SHING, AUDREY
DOCTOR : P. AFSHAR
ALLERGIES : NO KNOWN ALLERGIES
Prepared : 06/20/23 By:RPh:AS Tech:
RX DATE : 06/20/23
QTY DISPENSED: 2
HEIGHT :
WEIGHT : .00 lbs
Compound Lot#:

Example of original new order was processed, thus the prepared date and rx date are the same.

Compound Name.. IV-DAPTOMYCIN 850MG/50NS

Drug NDC	Description	Amount/Conc	M/U	Lot Number	Filler Init	Checker Init
1)00409-0122-01	DAPTOMYCIN 500 MG VIAL	3.40	VIA			
	Manufacturer: HOSPIRA/PFIZER					
	Expiration Date: 3/24					
2)00338-0049-31	SODIUM CHLORIDE 0.9% SOLUTI	100	ML			
	Manufacturer: BAXTER HEALTHCA					
	Expiration Date: 6/24					
3)00338-0049-11	SOD CHLORIDE 0.9% INJ	40	ML			
	Manufacturer: BAXTER HEALTHCA					
	Expiration Date: 6/24					

Information
Type: Compound
Group:

Total Amount: 143.40
Label Quantity:
Label Unit: BAG
Expiration Days: 2
Use By: 06/22/23

Category 1: IV
Category 2: IVG
Category 3:
Category 4:
Category 5:
Category 6:

Notes:
DOSE: 17ML=850MG

EQUIPMENT:ISO 7 IV CLEAN ROOM,ISO 5 IV HOOD

SUPPLIES:12 ML SYRINGE AND 1ML SYRINGE,NEEDLE, ALCOHOL SWAB

CLEAN ROOM GEAR: BOUFFANT CAP, MASK, GOWN, STERILE GLOVES, SHOE COVERS

PROCEDURES:

COMPLETE IV COMPOUNDING RECORD SHEET. PHARMACIST TO VERIFY DOSE AND CALCULATIONS. INSPECT VIALS AND SUPPLIES ARE FREE OF PARTICLE AND DISCOLORATION.WIPE RUBBER TOPS WITH ALCOHOL. RECONSTIUTE 2 VIALS OF 500MG DAPTOMYCIN WITH 10ML NORMAL SALINE TO EACH VIAL. TO MINIMIZE FOAMING, AVOID VIGOROUS AGITATION OR SHAKING OF THE VIAL DURING OR AFTER RECONSTITUTION. ENSURE THAT ALL POWDER IS WETTED BY GENTLY ROTATING THE VIAL. ALLOW THE WETTED PRODUCT TO STAND UNDISTURBED FOR 10MINS. GENTLY ROTATE OR SWIRL THE VIAL CONTENTS FOR A FEW MINUTES AS NEEDED TO OBTAIN A COMPLETELY RECONSTITUTED SOLUTION. THEN WITHDRAW

Compound Worksheet

CRAIG PATERSON PAGE: 2

RX NUMBER: 09448527 RX DATE: 06/20/23 DRUG DISP: IV-DAPTOMYCIN 850MG/50NS

AND ADD 17ML TO 50ML NS BAG.

INSPECT FINAL COMPOUNDED SOLUTION FOR ANY
PRECIPITATION AND ABNORMAL DISCOLORATION.
PHARMACIST TO PERFORM FINAL REVIEW AND QUALITY
CHECK OF FINAL PRODUCT.

STORAGE AND STABILITY:REFRIGERATED AND DISCARD
AFTER 2 DAYS,ROOM TEMPERATURE DISCARD AFTER 12HRS

REFERENCE:

USP CHAPTER 797,2019

LEXICOMP

STERILE COMPOUNDING AND ASEPTIC TECHNIQUE:
CONCEPTS, TRAINING AND ASSESSMENT FOR PHARMACY
TECHNICIANS

PACKAGE INSERT

RPH _____ DATE 6/20/23

Administration information

Route: 404817000	Date/Time Tracking: N	Authorized:
Access:	Last Date: 00/00/00	Dispensed:
Dosage: 11	Last Time:	

Directions: INFUSE 856MG (67ML) OVER 30MINS (134ML/HR) EVERY
24 HOURS UNTIL 6/22/23

Compound Worksheet

CRAIG PATERSON PAGE: 3

RX NUMBER: 09448527 RX DATE: 06/20/23 DRUG DISP: IV-DAPTOMYCIN 850MG/50NS

Billing information

Price Plan: GEN IV Medicare Procedure Code:

Billing NDC: - - Medicaid Procedure Code:

Billing Unit: 1

Source: VILLA

Original document #: 14061524 received on 6/19/2023 8:29 PM PDT

Resident: TURNER, ROBERT L (3021) Ordered By: Shorebiam, Andro Page 4 of 5
Location: STATION 2 05 C National Provider ID #1073711453

Order Date: 06/19/2023 19:00
Communication Method: Phone
Order ID: 12751732
Order Summary: Tylenol Tablet 325 MG (Acetaminophen) Give 2 tablet by mouth every 4 hours as needed for PAIN 1-10 NOT TO EXCEED 3 GMS ACETAMINOPHEN IN 24 HOURS/9 TABS FROM ALL SOURCES**DOCUMENT SITE AND PAIN LEVEL**GIVE WITH FOOD OR MILK**BLACK BOX WARNING**
Confirmed By: Dharamjit Kaur (RN)

Order Date: 06/19/2023 19:00
Communication Method: Phone
Order ID: 12751731
Order Summary: Vitamin C Tablet (Ascorbic Acid) Give 500 mg by mouth one time a day for SUPPLEMENT
Confirmed By: Dharamjit Kaur (RN)

CRCR 52.1
NO DOSE ADJ
NEEDED

Order Date: 06/19/2023 19:58
Communication Method: Phone
Order ID: 12751574
Order Summary: Ertapenem Sodium Solution Reconstituted 1 GM Use 1 gram intravenously every 8 hours for ESBL IN URINE for 10 Days
Confirmed By: Dharamjit Kaur (RN)

PER JEET OK TO USE MINI BAG PLUS FOR ERTAPENEM

Order Date: 06/19/2023 20:01
Communication Method: Phone
Order ID: 12751723

CHART CONTROL COPY

ATTACH ORIGINAL SIGNED COPY WHEN RECEIVED

Co

ORIGINAL COPY

Telephone Orders

PHYSICIAN/PRESCRIBER PLEASE SIGN AND RETURN WITHIN 48 HOURS

☐ Send NO MEDS ☐ Send ALL MEDS ☐ Send * MEDS ONLY ☐ ____ Doses taken from Emergency/Backup Stock ☐ When available/next routine delivery: ☐ Stat ☐ ____

Facility Name	Address	Signature of Nurse Receiving Order	Date/Time
Villa Health			

Family Name	First Name	DOB	Admission Number	Room Number	Attending Physician
Turner,	Robert				

Date Ordered	Time Ordered	Date D/C'd	MEDICATION/Order	Dose & Form	Route	Schedule	INDICATION - DX
6/19/23			Clarification re mini bag plus for Ertapenem 1gm				
			OD x 10 days				
			D.O. Dr. Shorebiam (Cinq Anus)				

Physician/Prescriber Signature | Title | Date

NURSE: Please Initial This Documentation Record As Performed

Pharmacy	On Physician's Order Sheet	Med Sheet	TX Sheet	Nurse's Notes	Patient Care Plan	ADL/Flow	Signed	Date	Time
☐ Courier ☐ Faxed (Fax Original) ☐ Phone									

Signed Date:

2023-06-19 20:28 1 2 >> 0401 Med Plus Pharma P 4/5

Allergies:

RPh Initials:

BUN 18 CREA 1.1 (6/16/23)

HT/WT /145#

MP ltc ©

IV LOG

RX # 9448360 06/19/23 IJ
TURNER, ROBERT
ERTAPENEM 1 GRAM VIAL

RN TO ATTACH 1GM VIAL TO NS.50ML BAG PRIOR TO INFUSION; THEN MIX & INFUSE IVPB OVER 30MINS (100ML/HR) EVERY 24 HOURS FOR 10 DAYS

NDC# 44567-0820-10 RPh: PH Tech: NR

MP ltc © MED-PLUS PHARMACY LTC
760 ARROW GRAND CIRCLE
COVINA, CA 91722
866-463-3757

WG CRITICAL CAR

Qty: 1 1.0000 NEW
VILLA HC (25)
Prescriber: SHAROBIEM,A 2005C
Black Box Warning: N VIL
Ins: MEDD PRIME/MDP RF: 00

VIL REORDER
RX # 9448360
ERTAPENEM 1 GRAM VIAL
TURNER, ROBERT

RX # 9448361 06/19/23 IV
TURNER, ROBERT
SODIUM CHLORIDE 0.9% SOL+50ML

RN TO ATTACH 1GM ERTAPENEM VIAL TO NS.50ML BAG PRIOR TO INFUSION; THEN MIX & INFUSE IVPB OVER 30MINS (100ML/HR) EVERY 24 HOURS FOR 10 DAYS

NDC# 00338-0553-11 RPh: PH Tech: NR

MP ltc © MED-PLUS PHARMACY LTC
760 ARROW GRAND CIRCLE
COVINA, CA 91722
866-463-3757

BAXTER HEALTHCA

Qty: 50 50.0000 NEW
VILLA HC (25)
Prescriber: SHAROBIEM,A 2005C
Black Box Warning: N VIL
Ins: MEDD PRIME/MDP RF: 00

VIL REORDER
RX # 9448361
SODIUM CHLORIDE 0.9% SOL+
TURNER, ROBERT

Discard After: 07/04/23
Batch Number:

START DATE	DC DATE	TOTAL DOSES
6.20.23 9AM		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15

16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
			1	0											

IV PUMP ___YES / ___NO PUMP SERIAL NUMBER _____

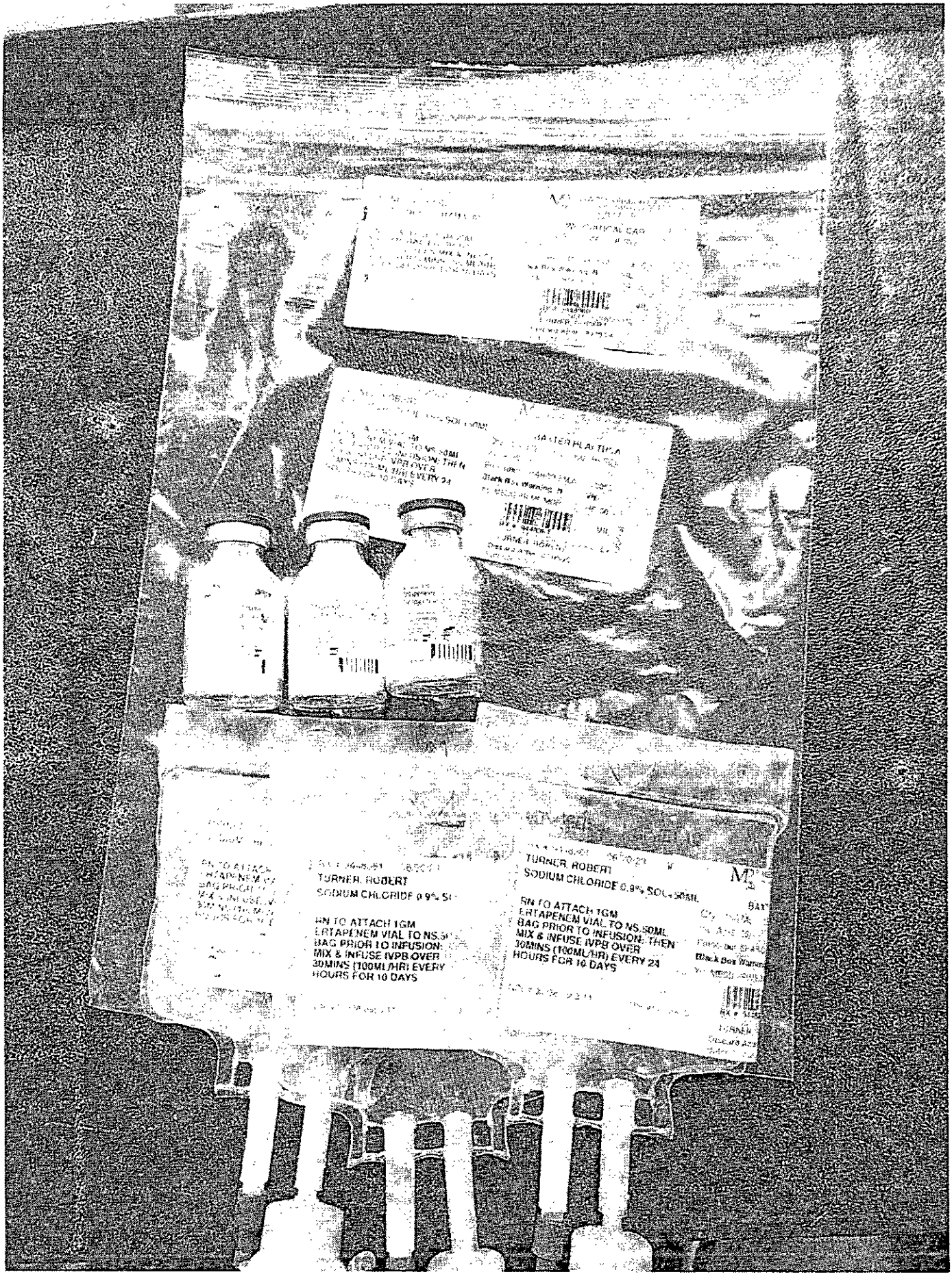
COMMENTS

INGREDIENTS USED

Name of Drug/Soln	Lot #	Exp. Date	M/g	Quantity

FINAL PRODUCT

Rx #	BUD	Date Disp.	# Bags	Rx #	BUD	Date Disp.	# Bags


TURNER, ROBERT
SODIUM CHLORIDE 0.9% SOL-50ML
RN TO ATTACH 1GM
ERTAPENEM VIAL TO NS 50ML
BAG PRIOR TO INFUSION. THEN
MIX & INFUSE IVPB OVER
30MINS (100ML/HR) EVERY 24
HOURS FOR 10 DAYS
TURNER, ROBERT
SODIUM CHLORIDE 0.9% SOL-50ML
RN TO ATTACH 1GM
ERTAPENEM VIAL TO NS 50ML
BAG PRIOR TO INFUSION. THEN
MIX & INFUSE IVPB OVER
30MINS (100ML/HR) EVERY 24
HOURS FOR 10 DAYS

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INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 6/19/2023 Inspector: Suzy Patell

Firm: MED-PLUS PHARMACY Phone: (866) 463-3757

Address: 760 ARROW GRAND CIR City: COVINA Zip: 91772

Ownership: CORPORATION

Permit #: LSC101776 PHY58706 Permit Exp: 8/1/2023 DEA#: FM2048090 DEA Exp: 1/31/2025

Date of Self Assessment Form: 9/7/2022 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 24Hr Hours Saturday 24Hr Hours Sunday: 24Hr

PIC FLYNN H LEW RPH37120 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:
STANLEY W GOLDENBERG	RPH25720
ALBERT C WON	RPH75811
ANNA M CHAN	RPH65792
AUDREY T SHING	RPH52382
CELESTE HA	RPH54688
CHARISSA C ONG	RPH78246
EVA F MAGBUHOS	RPH74323
JOHN S DIBBINI	RPH83778
MAHA A ELSERAFI	RPH81389
LYNNA LE	RPH85324
MALLERY T SY	RPH74237
OFELIA R RENTORIA	RPH45104
PETER H HANNA	RPH81583
SAMEH LOTFY ABD S KHALI	RPH66921
TAMER F DIMIAN	RPH58134
TIFFANY L NGUYEN	RPH58015
DINA A MUSTAFA	INT45038
SARA N ALTOWAIJI	INT44984

Staff Name:	License #:
AILEEN T FUKASAWA	TCH90094
ALANEE A PINEDO	TCH188209
AMBER T VARGAS	TCH50828
ANDREA N ENRIGHT	TCH136603
BINH LE	TCH55217
BRIANA J SANCHEZ	TCH153600
CHRISTINE MARIE P CONNOR	TCH154641
CHUONG H LUONG	TCH59837
DEJANE R QUINTANA	TCH171335
DIANA D PINEDO	TCH187963
EDGAR F GARCIA	TCH40169
EDGARDO SANCHEZ GAONA	TCH113910
FERDINAND S BUNDA	TCH27820
GEMMA B LAGASCA	TCH14700
GIOVANNI REYES	TCH183634
HERIBERTO M MEJIA	TCH54638
INGRID A CONTRERAS	TCH133688
JAMIE WALDIE	TCH39470
JASMINE M PRICE	TCH33031
JEANETTE D LAW	TCH145314
JEANETTE M FLIEHLER	TCH165126
JONATHAN CRUZ	TCH77184
JOSELITO V RECINTO	TCH60516
JOSEPH V DEL VALLE	TCH9066

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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

JUAN C CUCAL	TCH148143
KELLY Y TRIGUEROS	TCH95121
KEVIN CONTRERAS	TCH93207
MABEL A RODRIGUEZ	TCH178095
MARIA M GALLEGOS	TCH34726
MARIA T CONTRERAS	TCH8517
MARICELLA A VILLASENOR	TCH183435
MARTHA MEDINA-CONTRER	TCH49290
MARTIN J CHOW	TCH89903
NATHAN L RAMIREZ	TCH140701
NEOLANNI A WOODS	TCH175262
NORMAN J NICHOLS	TCH108505
RALPH M GOMEZ	TCH126129
RAVEN A SANCHEZ	TCH143860
RAYMOND E SOTO	TCH96385
REBECCA A MONTENEGRO	TCH178888
REZZIE C MEDALLA	TCH133888
RICARDO OLIVA	TCH143056
ROBERT P LUCERO	TCH146879
RUDOLPH P ORTIZ	TCH42820
RUFINA M BANZUELA	TCH6375
RUTH TEZAGUIC PEREZ	TCH180666
SCOTT E HARRISON	TCH20027
SHANNEE E GOODWIN	TCH143902
STACY A MAYEDA	TCH14920
SUSIE G PEREZ	TCH14250
TERESITA G DE JESUS	TCH2786
THAIS ROMERO-VARELA	TCH179013
VICTOR E ROMERO	TCH20420
VILMA D SANTELLAN	TCH48830
VIRGINIA BRACAMONTES RI	TCH180939
YANCY V UY	TCH29063
YASMIN MENDOZA	TCH171500

Inspector Remarks:

Closed door outpatient pharmacy located in a business park, servicing about 200 SNFs. CSPs compounded in a prefabricated structure within pharmacy warehouse area. Inspection conducted with PIC Flynn Lew, RPH Audrey Shing and TCH Gemma Lagasca. Per PIC, about 2 CSPs compounded daily. Practice of providing unspiked piggy bags, minibag plus devices, and antibiotic vials and the labeling thereof, discussed with PIC and education provided for labeling each ingredient supplied with appropriate instructions for mixing, pursuant to a matching prescription for the unmixed ingredients rather than for the admixed IVPB. PIC to communicate a plan after review.
PIC Name and contact: Flynn Lew <flynn.lew@medpluslic.com> 866-463-3757 x1999
ADRs/**Waivers:** none per PIC

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INSPECTION REPORT

Documents reviewed: 6/14-6/16/2023
Date of Inspection: 6/19/2023

LSC RENEWAL INSPECTION:
Compounding Area: ISO 8 positive pressure anteroom with clean/dirty sides, sink, eyewash, garbing, rack and cleaning supplies, leads to a positive pressure ISO 7 non-HD buffer room with carts, an ISO 5 LFW and a passthrough window with interlocking door connecting to the non-ISO classified pharmacy. Per PIC, the pass through is cleaned, but never used. Advised labeling the pass through as non-usable, to ensure compliance with PIC's instructions, by all pharmacy staff.
Certification/Smoke pattern video: via CRS 2/2/2023. Smoke video of PEC provided to view.
Environmental viable sampling: viable volumetric air and surface sampling in all ISO classified areas, via CRS- last 2/2/2023. In-house surface sampling in PEC available and reviewed with RPH Shing. Discussed compliance with upcoming USP 797, effective 11/1/2023.
Hazardous Drugs Compounding: none, per PIC.
Record Keeping Requirements:

- Master Formula: in table format. Reviewed for ertapenem and discussed BUDs based on stability, sterility
- Compounding Worksheets: reviewed for ertapenem, micafungin. Date prepared and Rx date are inaccurate. Documentation of quality reviews and post compounding steps by RPH unavailable. PIC to review and provide plan of compliance with documentation of reviews, steps and date compounded on compounding log.
- Label: date compounded; 'compounded by' notification; storage: available on CSPs. Label for ceftriaxone dispensed as separate vials, bags and minibag plus adapters but labeled with instructions for infusion, and not instructions for mixing. Rx order is for admixed ceftriaxone, per PIC. Please review and advise on changes to be made to practice, labeling, prescription orders.
- Cleaning Documentation: daily, weekly, monthly cleaning logs reviewed- use of PeriDox monthly and PeriDox/PreEmpt daily in weekly alternating cycles noted.
- Refrigerator/Freezer/Room/Incubator Temp., Pressure: Excel logs available. Continuous monitoring w/notification via GoVee, and audible alarm for pressure available in 24 hour pharmacy.
- Training: written, video, gloved finger tip sampling, medium risk media fill, observational validation provided for RPH Tiffany Nguyen was reviewed and lack of observational validation of demonstrated daily, weekly, monthly cleaning tasks pointed out to PIC. Please remedy for all compounding staff and their supervising RPHs.

Protective Clothing: observed during inspection and reviewed in training
Policy and Procedures: PIC tasked with review and revision based on current practice and current regulations.

- Actions when viable sampling levels are exceeded: Please review as discussed
- Training of staff: Please revise based on gaps in administered competencies for RPH Nguyen.
- Hand hygiene and garbing: available
- Cleaning of Facilities/Equipment: spot checked.
- Annual review by PIC: completed 6/14/2023, per PIC. Education provided on reviewing P&Ps against regulations and practice to gauge compliance with the stricter standards.
- Recall of compounded drugs; ADRs: available. Please review and revise for definition of ADRs, recall of CSPs compounded by pharmacy which fall below minimum standards of integrity potency, quality and labeled strength, and for notification to Board.
- Documentation used to determine BUD: Please revise to current strictest standards.
- Qualitative/Quantitative Analysis/frequency: Policy requires testing annually. PIC educated on current standards requiring more than one qualitative and quantitative analysis per year. Please revise. Practice is to send 2 CSPs annually (twice a year) for potency, sterility and endotoxin testing- results from January and May 2023 from ARL available for review.

Education: New USP 797, 800 enforceable 11/1/2023 for facility requirements, viable sampling, activities considered as compounding

DISCUSSION:

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INSPECTION REPORT

Please provide the following to Inspector Patell at suzy.patell@dca.ca.gov, no later than 6/24/2023:
1. Plan of compliance with accurate documentation of the date a CSP is compounded on each compounding record.
2. Changes made to practice of minibag plus adapter, bag and vial dispensing to comply with labeling, prescription orders. Please provide an example to illustrate.
3. Revised P&Ps for: BUD determination; Quality assurance for end product testing; Recalls; ADRs: actions when viable sampling levels are exceeded.

Licensee Remarks:

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Flynn Lew

Inspector (sign) _____

Inspector (print) Suzy Patell

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/21/2023

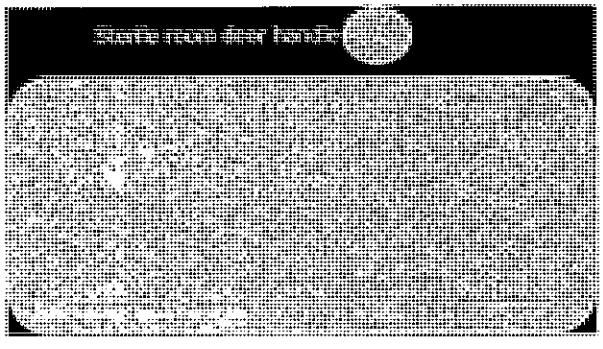
PURPOSE:

- To evaluate work surface cleaning and disinfection procedures, and staff competency. Potential sources of contamination in the compounding areas include improperly disinfected work surfaces, inadvertent touch contact by compounding personnel, damaged HEPA filters, improper room ventilation, and changes in personnel garbing procedures. Surface testing highlights conditions contributing to excessive microbial and particulate levels due to ineffective cleaning or personnel/equipment issues.

GENERAL POLICY:

- Surface sampling shall be completed in all ISO classified areas monthly.
- Sampling shall be performed at the end of compounding with QI EnviroTest™ Media Paddles for the sampling. Once sampling has occurred, plates are incubated to promote growth, the microorganisms are counted, and results reported as the number of colonies forming units (CFUs) per area sampled.
- Surface sampling must be performed at the end of compounding activity or shift, but before the area has been cleaned and disinfected.
- For each classified area the sampling, testing, cleaning, and retesting must be conducted monthly.

  ➢ Locations to be sampled are:



  Viable Outer Hood Surface
  - Right Hand Surface-HS1
  - Center Hand Surface- HS2
  - Left Hand Surface – HS3

  Viable Inner Hood Surface
  - Right Hand Surface - VA1
  - Center Hand Surface -VA2
  - Left Hand Surface -VA3

  Viable Outside Hood (sterile room door handle) - VA4

- Results shall be reported as CFU per unit of surface area.
- Any CFU growth reported shall prompt an immediate review of policies and procedures, staff competency and air filtration efficacy within the aseptic compounding area. Deficiencies shall be corrected as soon as possible.

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/21/2023

- If microbial growth is elevated consistently, a review of garbing, cleaning and compounding practices shall be performed and documented with follow up personnel training.

- CFU counts that exceed the action level shall be reported to the Pharmacist-in-Charge.

PROCEDURE

1. Surface Sampling
   1.1 Flat surfaces: Surface collection with use of contact plates is by gently pressing the media paddle surface plate to the sample surface. Using a rolling motion, with a light uniform pressure, to ensure that the entire surface of the paddle will contact the sample surface. Immediately following the sampling, the area shall be thoroughly wiped with a non-shedding towel soaked in sterile 70% IPA.
   1.2 Irregular surfaces: A sterile, cotton-tipped swab is moistened with sterile water and swabbed over such surfaces and into the corners of equipment. For other irregular surfaces, the swab should be rubbed over a surface area roughly the same size as the base of the contact plate three times in an opposite direction between each successive stroke. Following sampling, the swab head should be gently rotated over the surface of the media paddle three times, again rolling in opposite direction between each successive stroke.
   1.3 After collecting each sample, it is then placed in its container, sealed shut, and labeled.
   1.4 After sampling, the sampled area must be thoroughly cleaned and disinfected.

2. Incubation and Counting

   2.1 The media paddles are placed in an incubator.

      2.11 30°-35°C (86°-95°F) for no less than 48 hours, examine and record, THEN

      2.12 20°-25°C (68°-77°F) for no less than five (5) additional days, examine and record

   2.2 After incubation, the plates are removed from the incubator and the colonies counted. Record the total number of discrete colonies of microorganisms on each device as CFU per sample on the environmental sampling form. Note that counting areas containing a profuse growth may lead to considerable error.

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
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2.3 Spreading colonies should be counted as one, but care should be taken to observe other distinct colonies intermingled in the growth around the plate periphery or along a hairline. These should also be counted as one colony, as should be colored colonies and halo-type spreaders.

2.5 After the colony counting results are documented, the paddles are placed in a biohazard bag and disposed of accordingly.

2.6 When testing is completed for ISO Class 5 devices or hoods, clean the hood and test areas with sterile 70% isopropyl alcohol.

2.7 Colony counts exceeding recommended action levels for microbial contamination shall be met with remedial action. Recommended action levels with regard to ISO classification with surface sampling include:

2.7.1 ISO Class 5: >3 cfu per contact plate;
2.7.2 ISO Class 7: >5 cfu per contact plate; and
2.7.3 ISO Class 8 or worse: >50 cfu per contact plate.

If levels measured during surface sampling exceed the levels listed above, an attempt must be made to identify any microorganism recovered to the genus level.

2.8 The Pharmacist-In-Charge or designee shall determine the course of action to resolve any problems of this nature. The corrective action plan must be dependent on the cfu count and microorganism recovered. Corrective actions include:

2.8.1 Process or facility improvements
2.8.2 Personnel training
2.8.3 Cleaning and disinfecting
2.8.4 HEPA filter replacement and/or repair.

2.9 Corrective Action Plan
2.9.1 Investigation extent shall be consistent with the deviation and include evaluation of trends.
2.9.2 Corrective action plan results shall be documented.
2.9.3

DOCUMENTATION

A Surface Testing Log is used to document results and shall be maintained in the pharmacy for a minimum of three (3) years.

SUBJECT: QUALITY ASSURANCE PROCEDURES	REFERENCE #1010
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	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/19/2023

POLICY:

1. Policy for the quality assurance procedures involved in the Compounding of Sterile Products (CSPs).

PROCEDURE:

1. Routine cleaning and disinfection of direct compounding areas to minimize surface contamination. (See reference section #1031, #1032, #1033, #1034)

2. Air quality testing of the direct compounding environment is conducted every 6 months by Certifying Agency (Cleanroom Certification Company) (see reference section #1028).

    a. Air quality testing of the immediate compounding area, i.e., laminar airflow workbench to ensure maintenance of ISO Class 5 air quality.

3. Surface Sampling is performed by IV pharmacy staff monthly and documented (see Attachment E).

4. Visual validation of compounding personnel wearing the appropriate personal protective equipment, gowns, head and shoe covers, masks, and goggles, as appropriate.

5. Documented review of physicians' orders and ingredients used, including correct amount of the ingredients.

6. Final product inspection for particulates, cloudiness, abnormal discoloration, package integrity, correct and complete labeling.

7. Media-fill tests, fingered glove test, hand hygiene and garbing observation, IV competency assessment and written exam performed and passed initially and twice-yearly by all compounding personnel. (see reference section #1004, #1005)

8. Process validation is verified by qualitative and quantitative end-product analysis for sterility, potency, and endotoxin twice yearly.

    a. End product testing is performed by a third-party laboratory.
    b. Samples are properly prepared and are verified by pharmacist at each step.
    c. Samples are then sent for third party quantitative and qualitative analysis.
    d. Results are reviewed by the Pharmacist in Charge, IV Supervisor Pharmacist and IV Supervisor Technician.
    e. If results are outside of the acceptable range – processes are reviewed, and a new sample is resubmitted for validation of the processes.

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SUBJECT: BEYOND USE DATES	REFERENCE #1047
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 06/04/20
APPROVED BY: FLYNN LEW PHARM.D.	REVISED: 06/22/23

POLICY:

A. Assigning beyond-use dates (BUD) for CSPs is based on parameters that may affect quality, and the achievement and maintenance of sterility.

B. Determining BUD for CSP

1. Quality may be affected by the following parameters:

   a. Chemical and physical stability properties of the drug and or its formulation

   b. Materials of composition of the container closure system and compatibility of the container closure system with the final preparation (e.g., leachable, interactions, adsorption, and storage conditions).

2. Sterility achievement and maintenance may be affected by the following factors:

   a. Conditions of the environment in which the CSP is prepared.
   b. Aseptic processing and sterilization method
   c. Starting components (e.g., sterile vs nonsterile ingredients)
   d. Whether or not sterility testing is performed
   e. Storage conditions (e.g., packaging and temperature).

3. Each CSP formula record shall note the appropriate storage conditions and the BUD assigned.

4. The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components.

SUBJECT: BEYOND USE DATES	REFERENCE #1047
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BEYOND-USE DATING FOR STERILE COMPOUNDED DRUG PREPARATIONS*

Compounding Environment	Sterility Testing Performed and Passed	Controlled Room Temperature (20°-25°C)	Refrigerated Storage (2-8°C)	Freezer Storage (-25°C to -10°C)
ISO Class 5 PEC in ISO Class 7 cleanroom (Category 2)	No	4 days	10 days	45 days
ISO Class 5 PEC in ISO Class 7 cleanroom (Category 2)	Yes	30 days	45 days	60 days

- *Prepared from only sterile starting components.*

SUBJECT: ADVERSE DRUG EVENTS REPORTING	REFERENCE #1057
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

PURPOSE:

To provide guidance on the reporting and review of Adverse Drug Events (ADEs) which includes adverse drug reactions and medication occurrences.

DEFINITION:

A. Adverse Drug Reaction
   a. Defined by ASHP (American Society of Heath-System Pharmacists), an adverse drug reaction is any unexpected, unintended, undesired, or excessive response to a drug that requires any of the following:
      i. Discontinuing, changing, or modifying the drug or dose
      ii. Hospital admission, prolonged stay, or supportive care or treatment
      iii. Significantly complicates, diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death.

B. Medication Occurrence
   a. Defined as an error in prescribing, verifying, dispensing, preparing, documenting, or monitoring a medication.

REPORTING:

A. Pharmacy Quality Assurance Program documentation

   a. Documentation of adverse drug reactions and medication occurrences
      i. Each documented report is reviewed and investigated.
      ii. Aggregate monthly quality assurance are periodically reviewed and trended
   b. Pharmacy personnel shall be informed of changes to existing pharmacy policy, procedures, or processes because of the quality assurance program.

B. Food and Drug Administration (FDA)
   a. FDA MedWatch program
      i. Program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.
   b. Reporting methods
      i. Completing FORM FDA 3500B
      ii. Phone: 1-800-FDA-1088
      iii. Fax: 1-800-FDA-0178

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0291
Expiration Date: 06/30/2025
(See PRA Statement below)

MEDWATCH
Consumer Voluntary Reporting (FORM FDA 3500B)

When do I use this form?

- You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

Don't use this form to report:

- Vaccines – report problems to the Vaccine Adverse Event Reporting System (VAERS).
- Investigational drugs or medical devices (those being studied) – report problems to your doctor or to the contact person listed in the clinical trial.
- Animal Drug, Device, Pet Food and Livestock Feed Problems – report problems to FDA's Center for Veterinary Medicine.
- Tobacco products – report health or product problems to the Safety Reporting Portal (SRP) https://www.safetyreporting.hhs.gov or call 1-877-287-1363.
- Food, cosmetic or dietary supplement products – report problems to the SRP https://www.safetyreporting.hhs.gov/SRP2.

Will the information I report be kept private?

The FDA recognizes that privacy is an important concern, so you should know:

- We ask only for the name and contact information of the person filling out the form in case we need more information.
- Your name and contact information may be shared with the company that makes the product to help them better understand the problem you are reporting, unless you request otherwise (see Section F).

What types of products should I use this form for?

- Prescription and over-the-counter drugs, therapeutic biologics and biosimilars including monoclonal antibodies, and biologics, such as human cells and tissues used for transplantation (for example, tendons, ligaments, and bone) allergenics and gene therapies.
- Medical devices, including any health-related kit, test, tool, or piece of equipment (such as breast implants, pacemakers, diabetes glucose-test kits, hearing aids, breast pumps, and many others)
- Cosmetics such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos
- Foods (including beverages and ingredients added to foods)

Are there specific instructions for filling out the form?

- Fill in as much information as possible and send in the report even if you do not have all the information.
- You can fill out this form yourself or have someone fill it out for you. If you need help, you may want to talk with your health professional.
- Feel free to include or attach an image of the product. Please do not send the products to the FDA.

How will I know the FDA has received my form?

- You will receive a reply from the FDA after we receive your report. We will personally contact you only if we need additional information.
- Your report will become part of a database so that it can be reviewed and compared to other reports by an FDA safety evaluator who will determine what steps to take.

How can I contact the FDA if I have questions?

Toll-free line: 1-800-332-1088
To report online: www.fda.gov/medwatch/report.htm

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

OMB Statement: "An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF ADDRESS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

MEDWATCH
Consumer Voluntary Reporting (FORM FDA 3500B)

Form Approved: OMB No. 0910-0291
Expiration Date: 06/30/2025
(See PRA Statement on preceding general information page)

Note: *For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jan-1900.*

Section A – About the Problem

1. What kind of problem was it? *(Check all that apply)*

- ☐ Were hurt or had a bad side effect *(including new or worsening symptoms)*
- ☐ Used a product incorrectly which could have or led to a problem
- ☐ Noticed a problem with the quality of the product
- ☐ Had problems after switching from one product maker to another maker

3. Date the problem occurred *(e.g., 01-Jan-1900)*

2. Did any of the following happen? *(Check all that apply)*

- ☐ Hospitalization – admitted or stayed longer
- ☐ Required help to prevent permanent harm
- ☐ Disability or health problem
- ☐ Birth defect
- ☐ Life-threatening
- ☐ Death *(include date) (e.g., 01-Jan-1900)*:
- ☐ Other serious/important medical incident

4. Tell us what happened, how it happened or why it happened. *(Include as many details as possible. FDA may reach out to you for any additional documents if necessary)*
Characters Remaining (max. 4,000):

For more information, visit http://www.fda.gov/MedWatch

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

5. Relevant Tests/Laboratory Results	Date *(e.g., 01-Jan-1900)*	Relevant Tests/Laboratory Results	Date *(e.g., 01-Jan-1900)*

Characters Remaining (max. 2,000):

Additional Comments

Section B – Product Availability

1. Do you still have the product in case we need to evaluate it? *(Do not send the product to FDA. We will contact you directly if we need it.)* ☐ Yes ☐ No

2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

For a problem with a product, including
- prescription or over-the-counter medicine
- biologics, such as blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical foods
- cosmetics or make-up products
- foods (including beverages and ingredients added to foods)

⇨ **Go to Section C**

For a problem with a medical device, including
- any health-related test, tool, or piece of equipment
- health-related kits, such as glucose monitoring kits or blood pressure cuffs
- implants, such as breast implants, pacemakers, or catheters
- other consumer health products, such as contact lenses, hearing aids, and breast pumps

⇨ **Go to Section D (Skip Section C)**

For a health or product problem with a food, cosmetic, dietary supplement or tobacco product

⇨ **Go to https://www.safetyreporting.hhs.gov/SRP2**

Section C – About the Products

1. This report is about ☐ Cosmetic ☐ Dietary Supplement ☐ Food/Medical Food ☐ Other

2. Name(s) of the product as it appears on the box, bottle, or package *(Include as many names as you see)*

3. Check if therapy is on-going ☐

4. Name(s) of the company that makes (or compounds) the product

5. Product Type *(check all that apply)*
☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar

6. Expiration date *(e.g., 01-Jan-1900)*	7. Lot number	8. NDC number

9. Strength *(for example, 800mg/160 mg or 20 mg)*

10. Quantity *(for example, 2 pills, 2 puffs, or 1 teaspoon, etc.)*	11. Frequency *(for example, twice daily or at bedtime)*	12. How was it taken or used *(for example, by mouth, injection, or on the skin)*?

13a. Date the person first started taking or using the product *(e.g., 01-Jan-1900)*:
13b. Date the person stopped taking or using the product *(e.g., 01-Jan-1900)*:
13c. Date the person reduced dose of the product *(e.g., 01-Jan-1900)*:

14. Give best estimate of duration Unit

15. Why was the person using the product? *(such as, what condition was it supposed to treat)*

16. Did the problem stop after the person reduced the dose or stopped taking or using the product? ☐ Yes ☐ No

17. Did the problem return if the person started taking or using the product again? ☐ Yes ☐ No ☐ Didn't restart

Go to Section E (Skip Section D)

Section D – About the Medical Device

1. Name of medical device

2. Name of the company that makes the medical device

3. Model number	4. Catalog number	5. Lot number	6. Serial number

7. Unique Device Identifier (UDI) number

8. Expiration date *(e.g., 01-Jan-1900)*	9. Was someone operating the medical device when the problem occurred? ☐ Yes ☐ No	If yes, who was operating it? ☐ The person who had the problem ☐ A health professional *(such as a doctor, nurse, or aide)* ☐ Someone else *(Please explain who)*

10. For implanted medical devices ONLY *(such as pacemakers, breast implants, etc.)*
Date the implant was put in *(e.g., 01-Jan-1900)*
Date the implant was taken out *(If relevant) (e.g., 01-Jan-1900)*

Go to Section E

For more information, visit *http://www.fda.gov/MedWatch*

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Section E – About the Person Who Had the Problem

1. Person's Initials

2a. Sex: Enter the patient's sex at birth (the sex that a person has or was assigned to at birth).
- ☐ Male
- ☐ Female
- ☐ Undifferentiated
- ☐ Decline to answer

2b. Gender: Enter the patient's current gender (how the patient thinks of themself).
- ☐ Cisgender man/boy (gender corresponds with birth sex)
- ☐ Cisgender woman/girl (gender corresponds with birth sex)
- ☐ Transgender man/trans man/ female-to-male (FTM)
- ☐ Transgender woman/trans woman/ male-to-female (MTF)
- ☐ Other gender category; please specify:
- ☐ Decline to answer

3. Age *(specify unit of time for age)*
- ☐ Year(s)
- ☐ Week(s)
- ☐ Month(s)
- ☐ Day(s)

4. Date of Birth *(e.g., 01-Jan-1900)*

5. Weight *(Specify lbs or kg)*
- ☐ lb
- ☐ kg

6. Ethnicity *(Choose only one)*
- ☐ Hispanic/Latino
- ☐ Not Hispanic/Latino

7. Race *(Choose all that apply)*
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

8. List known medical conditions. *(Such as diabetes, high blood pressure, cancer, heart disease, or others)*

Characters Remaining (max. 2,000):

9. Please list all allergies *(such as to drugs, foods, pollen or others)*

10. List any other important information about the person *(such as tobacco product use, pregnancy, alcohol use, etc.)*

11. List all current prescription medications and medical devices being used.

Characters Remaining (max. 2,000):

12. List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Characters Remaining (max. 2,000):

Go to Section F

Section F – About the Person Filling Out This Form

We will contact you only if we need additional information.

1. Last name	2. First name
3. Number/Street	4. City and State/Province
5. ZIP or Postal code	6. Country

7. Telephone number	8. Email address	9. Today's date *(e.g., 01-Jan-1900)*

10. Did you report this problem to the company that makes the product (the manufacturer/compounder)? ☐ Yes ☐ No

11. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

Send This Report by Mail or Fax

Keep the product in case the FDA wants to contact you for more information. Please do not send products to the FDA. Mail or fax the form to: MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852; FAX: 800-332-0178 (toll-free).

Thank you for helping us protect the public health.

For more information, visit *http://www.fda.gov/MedWatch*	**Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

DEFINITIONS

- The FDA has classified recalls according to the following guidelines:
- **Class I**: A situation in which there is reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death.
- **Class II**: A situation in which the use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III**: A situation in which the use of, or exposure to, a volatile product is not likely to cause adverse health consequences.

POLICY

- All recalled products would be removed from the compounding storage area, storage shelves and will-call area if a compounded prescription was compounded with the recalled product. The recalled product(s) will be quarantined until returned to the manufacturer or destroyed as per manufacturer instructions. In the event it is discovered that a compounded product does not pass our quality control, it is our policy to remove the product from out compounding area. In the event quality verification demonstrates the potential for adverse effects with continued use of the compounded drug product, patients who have received the compounded product would be notified and if possible, the compounded product would be recovered, in addition the prescriber and the state board of pharmacy will be notified.

PROCEDURES

- Identification of Product Recall Information: At our Pharmacy, product recall information is identified through several methods, including notification from the wholesaler, manufacturer, California State Board of Pharmacy and/or the FDA. Notification will typically be in written form via fax, e-mail, or mail.. This notification will be directed to or immediately forwarded to the Pharmacist-in- charge and/or compounding technician.

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 2 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

- Product Recall Assessment/Inventory Detection: Following receipt of recall information, the receiving party will determine if the product is stocked within the areas listed above.
- Recall Action/Information Dissemination
- Target Product Not Stocked: If the recalled product is not stocked, the following information is documented directly on the recall notice: identification of the product not being stocked, date, action, and initials of the reviewer. Records will be maintained in a binder.
- Target Product Stocked: Class II and III Recall:
- Identification: The pharmacist-in-charge and/or compounding technician will identify the location of the recalled medications
- Disposal/Return: Once the targeted item is identified the appropriate actions are taken in accordance with the manufacturer's recommendations and guidelines. The pharmacist-in-charge and/or compounding technician will supervise and ensure the removal of recalled product from stock immediately, quarantine and disposal/return via recall guidelines.
- Documentation: Retrieval and disposal/return of recalled product will be documented on the recall form sent from the manufacture/wholesaler by the pharmacist- in-charge and will include: date, recall classification, return date, quantity of stock, disposition, and initials. Records will be maintained in a binder
- Target Product stocked : Class I Recall - Because Class I recalls can have serious health consequences; the following additional measures will be taken in such cases
- Identification: The pharmacist-in-charge and/or compounding technician will identify the location of the recalled medications.
- Disposal/Return: Once the targeted item is identified the appropriate actions are taken in accordance with the manufacturer's recommendations and guidelines. The pharmacist-in-charge and/or compounding technician will supervise and ensure the removal of recalled product from stock immediately, quarantine, and disposal/return via recall guidelines
- Documentation: Retrieval and disposal/return of recalled product will be documented on the recall form sent from the manufacture/wholesaler by the pharmacist-in-charge and will include: date, recall classification, return date, quantity of stock, disposition, and initials. Records will be maintained in a binder.

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 3 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

- Identification of Patients Receiving Recall Medication: The pharmacy will identify, via the pharmacy computer system, a list of patients who potentially received the targeted product. The pharmacy will then attempt to contact each patient by phone and/or by mail if the patient cannot be reached by phone.

- Notification
  - Issuance of a recall notice of a sterile compounded drug notice shall be done as soon as possible and notifications of the following entities, within 12 hours of the recall notice release:
    - Prescriber
    - Patient
    - State Board of Pharmacy
  - The 12-hour notification is mandated if: use of or exposure to the recalled drug may cause serious adverse health consequences or death within the state of California.

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 58706

NAME: MED-PLUS PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

760 ARROW GRAND CIR
COVINA CA 91722
LOS ANGELES COUNTY

ISSUANCE DATE

AUGUST 31, 2022

EXPIRATION DATE

AUGUST 1, 2024

CURRENT DATE / TIME

JULY 10, 2023
9:14:26 AM

LICENSE RELATIONSHIPS

NAME: MED-PLUS PHARMACY

LICENSE/REGISTRATION TYPE: STERILE COMPOUNDING PHARMACY

LICENSE NUMBER: 101776 **PRIMARY STATUS:** CLEAR

ADDRESS :
760 ARROW GRAND CIR
COVINA CA 91772
LOS ANGELES COUNTY

NAME: LEW, FLYNN HAY

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 37120 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM2048090	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	09-08-2022

POLARIS PHARMACY SERVICES
760 ARROW GRAND CIR
COVINA, CA 91722

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FM2048090	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY-COLLECTOR	09-08-2022

POLARIS PHARMACY SERVICES
760 ARROW GRAND CIR
COVINA, CA 91722

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: POLARIS PHARMACY SERVICES

Pharmacy/Wholesaler License # (if applicable): 04544

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 866-463-3757 Website: www.medplusltc.com

Licensing Company Email: ghunt@polarisrx.com

Section 2: Personal Information

First: FLYNN Middle: Last: LEW

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addre[redacted]ARROW GRAND CIRCLE

City: COVINA State: CA Zip: 91722

Telephone: [redacted] Email: FLEW@POLARISRX.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
USC SCHOOL OF PHARMACY		09/1978 - 06/1982	
Address	**City**	**State**	**Zip**
1985 ZONAL AVE.	LOS ANGELES	CA	90089
Diploma/Degree obtained, if any			
PHARM.D.			

School Name		From - To (MM/YY – MM/YY)	
USC		09/1976 - 06/1978	
Address	**City**	**State**	**Zip**
925 W 34TH STREET	LOS ANGELES	CA	90089
Diploma/Degree obtained, if any			
NONE			

School Name		From - To (MM/YY – MM/YY)	
VAN NUYS HIGH SCHOOL			
Address	**City**	**State**	**Zip**
6535 CEDROS AVE	VAN NUYS	CA	91411
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1982 - PRESENT	[redacted] ELKWOOD ST	WEST HILLS	CA	91304
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
POLARIS PHARMACY SERVICES (FORMERLY MED-PLUS PHARMACY)			07/2019 - PRESENT
Business Address	**City**	**State**	**Zip**
760 ARROW GRAND CIRCLE	COVINA	CA	91722
Phone	**Title**		**Number of Employed Hours**
866-463-3757	PHARMACIST-IN-CHARGE		40HRS/WK
Description of Duties			
PHARMACIST-IN-CHARGE			

Business Name			From - To (MM/YY – MM/YY)
SKILLED NUSRING PHARMACY			01/2014 - 07/2019
Business Address	**City**	**State**	**Zip**
900 WESTERN AVE	GLENDALE	CA	91201
Phone	**Title**		**Number of Employed Hours**
833-353-7273	PHARMACIST-IN-CHARGE		40HRS/WK
Description of Duties			
PHARMACIST-IN-CHARGE			

Business Name			From - To (MM/YY – MM/YY)
SKILLED NURSING PHARMACY			10/2017 - 07/2019
Business Address	**City**	**State**	**Zip**
16666 E JOHNSON DR	CITY OF INDUSTRY	CA	91745
Phone	**Title**		**Number of Employed Hours**
800-519-4767	CHIEF COMPLIANCE OFFICER		40HRS/WK
Description of Duties			
CCO ACTIVITIES FOR THE CORPORATE ENTITY			

Business Name			From - To (MM/YY – MM/YY)
OMNICARE CANOGA PARK			2006-01/2014
Business Address	**City**	**State**	**Zip**
8220 REMMET AVE	CANOGA PARK	CA	91304
Phone	**Title**		**Number of Employed Hours**
818-746-9800	PHARMACIST-IN-CHARGE		40HRS/WK
Description of Duties			
PHARMACIST-IN-CHARGE			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, FLYNN LEW, **certify that as the designated representative for**

POLARIS PHARMACY SERVICES,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. (1) I am at least 21 years of age;
3. (C) I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. (C) I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. (2) I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. (C) I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. (N) I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

FLYNN LEW

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-16-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

FLYNN LEW

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-16-2024

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of LOS ANGELES

I, FLYNN LEW, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/17/2024

Date

Subscribed and Sworn to before me this 17th day of JANUARY, 2024

Notary Public Signature

SHEINA SAQUILLO TRINIDAD
Notary Public - California
Los Angeles County
Commission # 2366965
My Comm. Expires Jul 21, 2025

(Seal)

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT **CIVIL CODE § 1189**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)
County of LOS ANGELES)

On JANUARY 17, 2024 before me, Sheina Saquillo Trinidad, Notary Public,
Date *Here Insert Name and Title of the Officer*

personally appeared FLYNN LEW
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

SHEINA SAQUILLO TRINIDAD
Notary Public - California
Los Angeles County
Commission # 2366965
My Comm. Expires Jul 21, 2025

Signature _____
Signature of Notary Public

Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____
Document Date: _____ Number of Pages: _____
Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Corporate Officer — Title(s): _____	☐ Corporate Officer — Title(s): _____
☐ Partner — ☐ Limited ☐ General	☐ Partner — ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer Is Representing: _____	Signer Is Representing: _____

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: POLARIS PHARMACY SERVICES

NV Pharmacy or Outsourcing facility license # (if applicable): 04544

Physical Address: 760 Arrow Grand Circle

City: Covina State: CA Zip: 91722

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 866-363-3757 Toll Free # (NAC 639.708, NRS 639.23286): 866-463-3757

Fax: 877-363-3757 Contact Email: ghunt@polarisrx.com

Website: www.medplusltc.com

Nevada Business License # (if applicable) PH04544

Supervising/Managing Pharmacist Name (NRS 639.220): Albert Won

Supervising/Managing Pharmacist NV Pharmacist Registration #: 19452

Name of Person with direct knowledge of compounding procedures: Flynn Lew

Email of Person with direct knowledge of compounding procedures: flew@polarisrx.com

Telephone of Person with direct knowledge of compounding procedures: 866-463-3757 x 1999

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☒ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Prospective drugs:
Aminoglycosides (tobramycin, amikacin, gentamicin)
Vanocomycin (non-standard strengths)
Amphotericin b
Cefazolin (non-standard strengths)
Cefepime (non-standard strengths)
Cefoxitin (non-standard strengths)
Ceftaroline (Teflaro)
Ceftazidime (non-standard strengths)
Zerbaxa (non-standard strengths)
Daptomycin
Ertapenem (non-standard strengths)
Primaxin (non-standard strengths)
Meropenem (non-standard strength

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

6. What laboratory performs this additional testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
All final release procedures will include a visual inspection for particulate matter and turbidity.

8. How often do you perform glove fingertip and medial fill testing?
Every 6 months per USP <797> guidance for all designated compounding personnel.

9. What is your policy if an employee fails a glove fingertip or media-fill test?
It will require repeating the didactic training and retesting. Repeat of the gloved fingertip and media fill testing for no fewer than three separate times.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
The designee must demonstrate knowledge and competency of core skills in the following: hand hygiene, garbing, cleaning and disinfection, calculations, measuring, and mixing, aseptic teechnique, use of equipment, proper documentation of the compounding process on compounding records, proper use of the PEC's, principles of movement of materials and personnel within the ISO Class 5 compounding area.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
See separate attachment

12. Who performs the sterile compounding process at your facility?
Designated IV technicians.

13. Who is responsible and accountable for the sterile compounding process at your facility?
The lead IV pharmacist supervisor, Audrey Shing.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Refrigerated items will be packaged and shipped in styrofoam shipping containers with ice bricks overnight to the destinations. Ice brick quantity is determined by established cold-chain studies.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Flynn Lew

Name of Person who Completed the Form

Pharmacist-In-Charge

Title

Signature (copies or stamps not accepted)

1-16-2024

Date

Board Use Only	Date Received: 1/24/24 Date Approved: _____ Approved By: _____

Polaris Pharmacy Services

STERILE COMPOUNDING/ANTE AREA QUALITY ASSURANCE ENVIRONMENTAL CLEANING MAINTENANCE LOG

IV HOOD CERTIFICATION DUE DATE:	MONTH:
	YEAR:

DAILY TASKS	CLEAN ROOM (WITH CLEANING AGENT)	ANTE-ROOM
	1. CLEAN INSIDE HOOD **CEILING * DIFFUSER * INSIDE HOOD WALLS (BACK TO FRONT) *REMOVE BAR THEN CLEAN BAR & HOOKS, REASSEMBLE* CLEAN HOOD COUNTER TOP & EDGE.* 2. CLEAN TRANSFER CART, (TOP TO BOTTOM) & CLEAN EMPTY BINS FOR IV ORDERS . 3. CLEAN HAND ANTISEPTIC DISPENSER 4.CLEAN PASSING THROUGH WINDOW OUTSIDE THEN INSIDE; TOP TO BOTTOM 5. EMPTY WASTE & WIPE WASTE HOLDER, REPLACE LINERS. 6. MOP CLEAN ROOM FLOOR **START WITH THE CORNERS FURTHEST AWAY FROM ENTRY DOORS TO MINIMIZE CROSS CONTAMINATION.* 7. CLEAN DOOR HANDLE	1. CLEAN TRANSFER CART 2. CLEAN HAND ANTISEPTIC DISPENSER 3.EMPTY WASTE & WIPE WASTE HOLDER, REPLACE LINERS . 4. CLEAN SINK AND FAUCET *(TOP TO BOTTOM)* 5. MOP ANTEROOM FLOOR **START WITH THE CORNERS FURTHEST AWAY FROM ENTRY DOORS TO MINIMIZE CROSS CONTAMINATION.* *6.CLEAN DOOR HANDLE*

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
TECH INITIAL																															
SOLUTIONS USED (TBI/PM)																															
Start Time solution applied																															
End Time solution removed																															

CLEANROOM & ANTEROOM: 1. CLEAN EXTERIOR OF HOOD **START TOP, SIDES & BACK. 2. CLEAN SUPPLY SHELF/BINS(eg: FOR NEEDLES, SYRINGES, IVPB)* 3. CLEAN EXTERIOR OF SINK & LEG

WEEKLY TASKS	WEEK 1	WEEK 2	WEEK 3	WEEK 4
TECH INITIAL/DATE/TIME				
SOLUTIONS USED (TBI/PM/PD)				
Start Time solution applied				
End Time solution removed				

MONTHLY TASKS	CLEAN ROOM: 1. CLEAN CEILING 1ST THOROUGHLY WITH APPROPRIATE DISINFECTANT, THEN CLEAN THE WALLS (FROM TOP TO BOTTOM SYSTEMATICALLY FROM THE FAR SIDE TOWARD THE NEXT WALL, CLEAN WALL DIRECTLY BEHIND HOOD, CLEAN WINDOW AND DOOR (TOP TO BOTTOM). 2. CHECK/CLEAN PRE-FILTER COVER (TOP TO BOTTOM).	ANTE-ROOM: 1. CLEAN CEILING 1ST THOROUGHLY WITH APPROPRIATE DISINFECTANT, THEN CLEAN THE WALLS (FROM TOP TO BOTTOM SYSTEMATICALLY FROM THE FAR SIDE TOWARD THE NEXT WALL, CLEAN WINDOW AND DOOR (TOP TO BOTTOM).	Refrigerator (R) Incubator (I): clean thoroughly with appropriate cleanser. Passing window outside(W)
TECH INITIAL/DATE/TIME			R ☐ I ☐ W
SOLUTIONS USED (PD)			R=__ I=__ W=

CHANGE PRE-FILTER EVERY 6 MONTHS	FEB	AUG

*ROTATIONAL CLEANING SOLUTIONS : **PD** (PeridoxRTU)[DT=3 min], **PM *** (PREEMPT RTU Disinfectant)[DT= 10 min], **TBI*** (TBI 3300 Disinfectant)[DT=1 min] ***CLEANING** AGENT*

*ROTATIONAL CLEANING SCHEDULE: **TBI** ALTERNATE WITH **PM** WEEKLY.*

*MONTHLY CLEANING SOLUTIONS: **PD**; WALL AND CEILING WITH PERIDOX AND ALCOHOL ONLY*

revised 11/01/2023

IV POLICIES AND PROCEDURES MANUAL

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1005	COMPOUNDING STAFF GLOVED FINGERTIP SAMPLING
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SUBJECT: DEFINITIONS AND ABBREVIATIONS	REFERENCE #1001
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APPROVED BY: SHABANA YASMIN	REVISED: 11/20/15

- Ante-Area: Space beyond the buffer area/clean room; ISO Class 8 or better; hand hygiene and donning personal protective equipment take place in the ante-area.
- Buffer Area/Clean Room: Where the primary engineering control is physically located. Preparation and staging occur in this area. At least an ISO Class 7 environment; access limited to trained staff.
- Critical Area: ISO Class 5 environment
- Critical Site: An opening that provides a pathway for contamination between a sterile ingredient/item and the environment or any surface in direct contact with the sterile ingredient/item and the environment contamination. Correlates with the time of exposure.
- Compounding Aseptic Containment Isolator (CACI): Provides an aseptic environment for compounding sterile preparations.
- Compounding Aseptic isolator (CAI): Form of isolator designed for compounding.
- CSPs: Compounded sterile preparations
- Direct Compounding Area (DCA): Critical area within the ISO Class 5 Primary Engineering Control.
- Primary Engineering Control (PEC): Device or room that is ISO Class 5 environment.
    - LAFWs:
        - Laminar airflow workbenches, includes horizontal flow clean benches and vertical flow clean benches
    - Compounding Aseptic Isolators (CAIs)
    - Compounding Aseptic Containment Isolators (CACIs)
    - Biological safety cabinets

SUBJECT: CSPs POLICIES AND PROCEDURES	REFERENCE #1002
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

POLICY:

- All compounding policies and procedure will follow USP General Chapter <797> Pharmaceutical Compounding - Sterile Preparations.
- The policies in this manual apply to healthcare professionals in institutions where sterile preparations are compounded, stored and dispensed.
- These regulations do not apply in situations where medications are compounded for immediate use, such as when nurses prepare IV solutions for immediate administration or when a satellite pharmacy prepares an urgent or emergency (STAT) IV dose.

SUBJECT: COMPOUNDED STERILE PREPARATIONS - OPERATING PROCEDURES MANUAL	REFERENCE #1003
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/20

POLICY:

A. The Pharmacy Department will have a standard operating procedures manual for compounded sterile preparations (CSPs).

B. Policies and procedures will reference USP <797> requirements, the most current literature available, and specific state regulations.

C. The Pharmacist-in-Charge will maintain, review and update the Sterile Compounding Policies & Procedure manual annually and as needed.

D. The manual will include a copy of the master formula record for each CSP prepared in the Pharmacy Department.

E. Each CSP formula record will include (not all inclusive):

1. CSP formula
2. Beyond-use date
3. Appropriate storage conditions

F. At a minimum the manual should address:

1. Access to buffer or clean area and appropriate activities conducted within the buffer or clean area
2. Traffic flow in and out of buffer or clean area
3. Management of supplies, including storage
4. Personnel attire and conduct required for the buffer or clean area
5. Cleaning and sanitizing activities

SUBJECT: COMPOUNDING STAFF GLOVED FINGERTIP SAMPLING	REFERENCE #1005
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

E. Media paddles shall be covered using aseptic technique and incubated per manufacturer instructions as follows:

1. 30-35ºC (86ºF to 95ºF) for a minimum of forty-eight (48) hours, THEN

2. 20-25ºC (68ºF to 77ºF) for a minimum of an additional five (5) days.

F. Immediately after sampling is done, the employee should remove and dispose of the gloves and perform hand hygiene.

G. Successful completion of the gloved fingertip sampling is zero (0) colony-forming unit (CFU). Results should be reported separately as the number of CFU's per hand. New infusion staff must complete successfully at least three (3) times.

H. Results should be read, documented and trended utilizing the *Gloved Fingertip Sampling Log*.

I. Action levels shall be triggered when a sample indicates three (3) CFUs or greater. The CFU action level for gloved hands shall be based on the number of CFUs on both gloved hands, not per hand. Follow up personnel education should include proper hand washing/hand hygiene, garbing procedures and general compounding procedures.

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
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DEPARTMENT: MED-PLUS PHARMACY IV	OF: 3
	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/21/2023

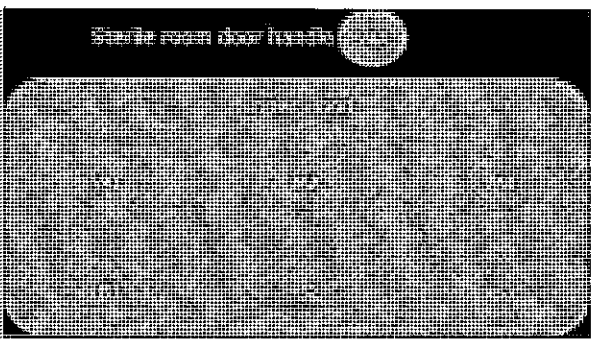
PURPOSE:

- To evaluate work surface cleaning and disinfection procedures, and staff competency. Potential sources of contamination in the compounding areas include improperly disinfected work surfaces, inadvertent touch contact by compounding personnel, damaged HEPA filters, improper room ventilation, and changes in personnel garbing procedures. Surface testing highlights conditions contributing to excessive microbial and particulate levels due to ineffective cleaning or personnel/equipment issues.

GENERAL POLICY:

- Surface sampling shall be completed in all ISO classified areas monthly.
- Sampling shall be performed at the end of compounding with QI EnviroTest™ Media Paddles for the sampling. Once sampling has occurred, plates are incubated to promote growth, the microorganisms are counted, and results reported as the number of colonies forming units (CFUs) per area sampled.
- Surface sampling must be performed at the end of compounding activity or shift, but before the area has been cleaned and disinfected.
- For each classified area the sampling, testing, cleaning, and retesting must be conducted monthly.

  ➢ Locations to be sampled are:



  Viable Outer Hood Surface
  - Right Hand Surface-HS1
  - Center Hand Surface- HS2
  - Left Hand Surface – HS3

  Viable Inner Hood Surface
  - Right Hand Surface - VA1
  - Center Hand Surface -VA2
  - Left Hand Surface -VA3

  Viable Outside Hood (sterile room door handle) - VA4

- Results shall be reported as CFU per unit of surface area.
- Any CFU growth reported shall prompt an immediate review of policies and procedures, staff competency and air filtration efficacy within the aseptic compounding area. Deficiencies shall be corrected as soon as possible.

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
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APPROVED BY: FLYNN LEW	REVISED: 06/21/2023

- If microbial growth is elevated consistently, a review of garbing, cleaning and compounding practices shall be performed and documented with follow up personnel training.

- CFU counts that exceed the action level shall be reported to the Pharmacist-in-Charge.

PROCEDURE

1. Surface Sampling
   1.1 Flat surfaces: Surface collection with use of contact plates is by gently pressing the media paddle surface plate to the sample surface. Using a rolling motion, with a light uniform pressure, to ensure that the entire surface of the paddle will contact the sample surface. Immediately following the sampling, the area shall be thoroughly wiped with a non-shedding towel soaked in sterile 70% IPA.
   1.2 Irregular surfaces: A sterile, cotton-tipped swab is moistened with sterile water and swabbed over such surfaces and into the corners of equipment. For other irregular surfaces, the swab should be rubbed over a surface area roughly the same size as the base of the contact plate three times in an opposite direction between each successive stroke. Following sampling, the swab head should be gently rotated over the surface of the media paddle three times, again rolling in opposite direction between each successive stroke.
   1.3 After collecting each sample, it is then placed in its container, sealed shut, and labeled.
   1.4 After sampling, the sampled area must be thoroughly cleaned and disinfected.

2. Incubation and Counting

   2.1 The media paddles are placed in an incubator.

      2.11 30°-35°C (86°-95°F) for no less than 48 hours, examine and record, THEN

      2.12 20°-25°C (68°-77°F) for no less than five (5) additional days, examine and record

   2.2 After incubation, the plates are removed from the incubator and the colonies counted. Record the total number of discrete colonies of microorganisms on each device as CFU per sample on the environmental sampling form. Note that counting areas containing a profuse growth may lead to considerable error.

SUBJECT: WORK SURFACE SAMPLING	REFERENCE #1006
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
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2.3 Spreading colonies should be counted as one, but care should be taken to observe other distinct colonies intermingled in the growth around the plate periphery or along a hairline. These should also be counted as one colony, as should be colored colonies and halo-type spreaders.

2.5 After the colony counting results are documented, the paddles are placed in a biohazard bag and disposed of accordingly.

2.6 When testing is completed for ISO Class 5 devices or hoods, clean the hood and test areas with sterile 70% isopropyl alcohol.

2.7 Colony counts exceeding recommended action levels for microbial contamination shall be met with remedial action. Recommended action levels with regard to ISO classification with surface sampling include:

2.7.1 ISO Class 5: >3 cfu per contact plate;
2.7.2 ISO Class 7: >5 cfu per contact plate; and
2.7.3 ISO Class 8 or worse: >50 cfu per contact plate.

If levels measured during surface sampling exceed the levels listed above, an attempt must be made to identify any microorganism recovered to the genus level.

2.8 The Pharmacist-In-Charge or designee shall determine the course of action to resolve any problems of this nature. The corrective action plan must be dependent on the cfu count and microorganism recovered. Corrective actions include:

2.8.1 Process or facility improvements
2.8.2 Personnel training
2.8.3 Cleaning and disinfecting
2.8.4 HEPA filter replacement and/or repair.

2.9 Corrective Action Plan

2.9.1 Investigation extent shall be consistent with the deviation and include evaluation of trends.
2.9.2 Corrective action plan results shall be documented.
2.9.3

DOCUMENTATION

A Surface Testing Log is used to document results and shall be maintained in the pharmacy for a minimum of three (3) years.

SUBJECT: COMPOUNDED STERILE PREPARATIONS (CSPs)	REFERENCE #1007
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

POLICY:

A. Compounded sterile preparations include those preparations that:

1. Any manipulation of a sterile product intended to produce a sterile final product.
2. The pharmacy does not utilize non-sterile ingredients in the preparation of a sterile final product.

B. Compounded sterile preparations also include the following that meet either of the above characteristics:

1. Biologics
2. Diagnostics
3. Drugs
4. Nutrients

SUBJECT: COMPOUNDED STERILE PREPARATIONS - OPERATING PROCEDURES MANUAL	REFERENCE #1003
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6. Use of laminar airflow workbenches (LAFWs) and/or compounding aseptic isolators (CAIs)
7. Traffic flow in the direct compounding areas (DCA)
8. Infection control and prevention techniques to decrease contamination potential
9. Environmental monitoring
10. Processing
11. Equipment
12. Finished preparation release checks and tests
13. Storage of CSPs
14. Beyond-use dates
15. Maintaining product quality
16. Quality assurance
17. Patient/caregiver education
18. Patient monitoring
19. Adverse events reporting

SUBJECT: STERILE COMPOUNDING - STAFF COMPETENCY	REFERENCE #1004
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

POLICY:

A. This Pharmacy Department shall demonstrate, assess, maintain and improve staff competency on an ongoing basis.

B. Competency assessment of staff is based on the following:

1. Patient population served

2. The specific competencies required by the pharmacy (safety, equipment, infection control)

3. The specific competencies that need to be assessed and reassessed on an ongoing basis, based on techniques, procedures, technology, equipment and skills needed to perform specified job responsibilities.

4. Only those individuals who are qualified through license, experience, and training to assess sterile compounding skills will conduct competency assessments

C. Compounding personnel will receive didactic instruction in the theory and practice of compounded sterile preparations before assuming compounding responsibilities.

1. Didactic written assessment test will be conducted annually.

2. Competence assessment for compounding personnel will include:

   a. Achieving and maintaining ISO Class 5 PEC devices
   b. Safety procedures
   c. Achieving and maintaining ISO Class 5 PEC devices
   d. CSPs:
      i. Identification
      ii. Accurate measuring, weighing, dilution and mixing of ingredients
      iii. Packaging
      iv. Labeling
      v. Storage
      vi. Dispensing
      vii. Transport
   e. Proper use and maintenance of all equipment

D. An observational assessment and media-fill tests for CSPs must be passed before assuming compounding responsibilities.

SUBJECT: STERILE COMPOUNDING - STAFF COMPETENCY	REFERENCE #1004
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

1. Observational assessment (gowning, cleaning, compounding) shall be conducted every 6 months.

    a. Hand hygiene and garbing practices related to the practices of compounding (see attachment A).

    b. Cleaning and disinfection of the ante-area, clean room and laminar airflow workbenches, CAIs, etc. (see attachment B)

    c. Working in the required conditions for aseptic processing and manipulation (see attachment C)

2. Media-fill tests

    a. Conducted every six(6) months for all sterile compounding personnel and infusion pharmacist.

E. When assessment activities (observation, written test, and media-fill tests) lead to a determination that an individual with performance abilities is unable or unwilling to improve, the staff member's work assignment may be revised. Further education and training will be required or other corrective action(s) may be taken.

    1. The staff member will not return to compounding duties until performance problems are resolved.

F. The competency assessment program is continuous and on-going with competency reports recorded and kept in a binder for review.

SUBJECT: COMPOUNDING STAFF GLOVED FINGERTIP SAMPLING	REFERENCE #1005
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

PURPOSE:

To evaluate staff competency for hand hygiene, donning personal protective equipment (PPE) and touch contamination.

POLICY:

A. Direct touch contamination by compounding personnel is the most likely cause of sterility problems with compounded sterile preparations (CSPs).

B. Sterile media paddles (agar-tryptose) shall be used in the fingertip sampling.

C. Sampling of compounding staff glove fingertips shall be performed before assuming compounding responsibilities. Compounding staff shall complete the gloved fingertip sampling competency three (3) times before beginning compounding responsibilities. (See Attachment D).

D. Fingertip sampling competency shall be performed and documented at least every six (6) months for those staff who compound CSPs, including infusion pharmacist.

E. Supervisory infusion technician or pharmacist shall use sterile contact media paddles to sample gloved fingertips, both hands, of compounding staff immediately after completing the handwashing/hand hygiene, and garbing procedure.

F. Successful completion of a fingertip sampling yields zero (0) CFU.

PROCEDURE:

A. Before sampling, each media paddle should be labeled with the compounder name or initials, the sampling date, and sampling hand (right or left).

B. Compounding personnel (compounder) shall be observed during the handwashing/hand hygiene and garbing procedures

C. Using aseptic technique, remove the lids of each media paddle.

D. Having the compounder lightly press or touch gloved fingertip (and thumb) into separate media paddles, one for the left hand and one for the right hand. Do not disinfect gloves prior to sampling as this may allow false negative results (i.e. cleaning with sterile 70% isopropyl alcohol is contraindicated for this test). When done correctly, a visible impression of each finger will be present in the agar.

SUBJECT: CSP CLASSIFICATION LEVELS	REFERENCE #1009
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/08/2020

POLICY:

A. The Pharmacist-in-Charge who oversees compounding activities is responsible for determining the classification level of CSPs prepared in the facility.

B. Classification level will be assigned according to USP <797> guidelines, applicable literature and the Pharmacist-in-Charge's professional judgment and experience.

C. Classification levels of CSPs are based on the conditions in which the products are prepared, the probability for microbial growth, and the time period within which they must be used.

1. Category 1

   a. CSPs are sterile preparations made in a segregated compounding area. The area consists of a single ISO5 PEC which is always located just **outside** of an ISO7 clean room.

   b. BUD Assignment
      i. CSPs assigned a BUD of 12 hours or less at room controlled temperature
      ii. CSPs assigned a BUD of 24 hours or less when refrigerated.
      iii. The BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components, regardless of source.

2. Category 2

   a. CSPs are sterile preparations made in a segregated compounding area. The area consists of a single ISO5 PEC which is always located **inside** of an ISO7, or better, clean room.

   b. BUD Assignment
      i. CSPs assigned a BUD of greater than 12 hours at controlled room temperature.
      ii. CSPs assigned a BUD of greater than 24 hours if refrigerated.
      iii. The BUD must not exceed the shortest remaining expiration date or BUD of any of the starting components, regardless of source.

SUBJECT: QUALITY ASSURANCE PROCEDURES	REFERENCE #1010
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	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/19/2023

POLICY:

1. Policy for the quality assurance procedures involved in the Compounding of Sterile Products (CSPs).

PROCEDURE:

1. Routine cleaning and disinfection of direct compounding areas to minimize surface contamination. (See reference section #1031, #1032, #1033, #1034)

2. Air quality testing of the direct compounding environment is conducted every 6 months by Certifying Agency (Cleanroom Certification Company) (see reference section #1028).

    a. Air quality testing of the immediate compounding area, i.e., laminar airflow workbench to ensure maintenance of ISO Class 5 air quality.

3. Surface Sampling is performed by IV pharmacy staff monthly and documented (see Attachment E).

4. Visual validation of compounding personnel wearing the appropriate personal protective equipment, gowns, head and shoe covers, masks, and goggles, as appropriate.

5. Documented review of physicians' orders and ingredients used, including correct amount of the ingredients.

6. Final product inspection for particulates, cloudiness, abnormal discoloration, package integrity, correct and complete labeling.

7. Media-fill tests, fingered glove test, hand hygiene and garbing observation, IV competency assessment and written exam performed and passed initially and twice-yearly by all compounding personnel. (see reference section #1004, #1005)

8. Process validation is verified by qualitative and quantitative end-product analysis for sterility, potency, and endotoxin twice yearly.

    a. End product testing is performed by a third-party laboratory.
    b. Samples are properly prepared and are verified by pharmacist at each step.
    c. Samples are then sent for third party quantitative and qualitative analysis.
    d. Results are reviewed by the Pharmacist in Charge, IV Supervisor Pharmacist and IV Supervisor Technician.
    e. If results are outside of the acceptable range – processes are reviewed, and a new sample is resubmitted for validation of the processes.

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SUBJECT: IMMEDIATE-USE CSPs	REFERENCE #1011
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The guidelines for immediate-use CSPs shall only be followed in the following events:
  - Cardiopulmonary resuscitation
  - Treatment in the Emergency Department
  - Preparation of diagnostic agents
  - Critical therapy:
    - When the preparation of a low-risk level CSP puts the patient at additional risk due to delays in treatment
- Medium-risk and high-risk level CSPs shall not be prepared as immediate-use CSPs.
- Immediate-use CSPs shall not be stored for anticipated needs or batch compounding.
- Immediate-use CSPs are excluded from the requirements for preparation of low-risk CSPs only when all of the following are met:
  - Compounding process involves simple transfer of three (3) or less commercially manufactured packages of sterile non-hazardous products and not more than two (2) entries into one (1) container of sterile infusion solution or administration container/device.
    - Chemotherapy agents are hazardous drugs and, therefore, shall not be prepared as an immediate-use CSP.
  - The compounding process is continuous and no longer than one (1) hour.
  - Aseptic technique is used during compounding.
  - If the CSP is not immediately administered to the patient, it is kept under constant surveillance to protect the CSP's sterility and to prevent mix-ups with other CSPs.
  - Administration of the CSP is within one (1) hour of the preparation of the CSP.

SUBJECT: IMMEDIATE-USE CSPs	REFERENCE #1011
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 2 OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- CSP label shall include:
  - Patient name
  - Patient MR#
  - Name(s) and amount(s) of all ingredients
  - Name or initials of the individual who prepared the CSP
  - The exact one (1) hour beyond-use date and time
- If the individual who prepared the CSP is the individual who immediately administered the CSP to the patient, labeling is not needed.
- If administration of the CSP does not occur within one (1) hour following the start of the preparation for the CSP, the CSP shall be discarded per policy and procedure.

SUBJECT: USE OF MULTIPLE DOSE VIALS (MDVs)	REFERENCE #1012
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The beyond-use date (BUD) for an opened or entered (i.e., needle-punctured) multiple dose container with antimicrobial preservatives shall be **28 days**, unless otherwise specified by the manufacturer.
- The healthcare provider shall write the expiration date on the vial, when opened.
- If the MDV does not have an expiration date on the vial or in the package insert, expiration will occur **28 days** after the vial has been opened, providing:
  - There is no obvious contamination.
  - Aseptic technique has been followed when withdrawing the medication.
  - The MDV is stored according to the manufacturer.
- Multiple dose vials shall be refrigerated after they are opened, unless contraindicated by the manufacturer.
- MDVs shall be discarded:
  - When empty
  - When suspected contamination occurs
  - When contamination/particulates are visible
  - When the manufacturer's established expiration date is reached, as long as the MDV has been stored according to manufacturer's instructions
- Multiple use of preservative-free MDVs will be avoided whenever possible.
- Opened single-dose ampuls shall not be stored for any period of time.

SUBJECT: USE OF MULTIPLE DOSE VIALS (MDVs)	REFERENCE #1012
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

PROCEDURE:

- The healthcare provider will perform hand hygiene before handling the multiple dose vial.
- A new, sterile needle and syringe shall be used each time medication is drawn from the vial.
- The integrity of the stopper shall be checked and the medication in the vial checked for any particulate matter prior to use. If the integrity of the stopper or sterility of the medication is in question, discard the vial.
- The stopper or vial gum shall be swabbed with 70% alcohol before each puncture.
- Avoid touching the stopper of the MDV during this process.
- The Pharmacy Department shall verify that MDVs are stored and labeled correctly when inspecting medication storage areas.

REFERENCES:

- USP <797> Guidebook to Pharmaceutical Compounding - Sterile Preparations, 2008
- Joint Commission Perspectives on Patient Safety, January 2006, "Switching to Single-Dose Containers, Moving Away From Multiple Dose Vials"
- Joint Commission Perspectives on Patient Safety, March 2006, "Errata: Multiple Dose Vials"

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
	PAGE: 1 OF: 5
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- All prospective employees must be informed that they may be required to work with antineoplastics. Note that this and the recommendations that follow apply to temporary staff as well as permanent staff. Supervisory staff shall review the procedures with their personnel. The toxic nature of antineoplastics shall be described to personnel in balanced terms. The rationale for each antineoplastic procedure or change in procedure shall be given. It should be noted that the procedures are felt to provide adequate safety, but that 100% protection cannot be guaranteed. All personnel must be informed that the procedures governing the handling of antineoplastics in the institution must be followed, and that adherence to these procedures will be monitored, and that noncompliance may result in disciplinary action.

- Under the US Environmental Protection Agency/Resource Conservation and Recovery Act (USEPA/RCRA), hazardous waste is a specific category of wastes that must be managed following a strict set of regulatory requirements. Of the large list of hazardous wastes, several were identified specifically as antineoplastic drugs; however, a number of drug formulations exhibit hazardous waste characteristics. Any drugs, including chemotherapy drugs utilized in this facility, meeting the criteria for hazardous drugs or with hazardous waste characteristics, will be managed according to the Occupational Safety and Health Administration (OSHA) standards, the Hazard Communication Standard, the Occupational Exposure to Hazardous Chemicals in Laboratories Standard and OSHA's Controlling Occupational Exposure to Hazardous Drugs guidelines.

    - Only those drugs determined to be hazardous agents will require management according to the federal hazardous chemicals standards listed above.

    - All other chemotherapy agents not identified as hazardous agents will be handled and disposed of as "simple" (i.e., not hazardous as identified by USEPA/RCRA standards) chemotherapy agents.

- Proper and timely medical treatment for acute antineoplastic exposures must be provided.

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

PROCEDURE:

- Only Pharmacy Department personnel specially trained and certified in chemotherapy handling will prepare or handle these drugs outside of the manufacturer's packaging.
  - Training shall occur before personnel prepare or handle hazardous drugs.
  - Training shall be ongoing.
  - Staff competency shall be assessed at least annually.
  - Training shall include:
    - Aseptic technique
    - Negative pressure techniques when using BSC or CACI
    - Proper use of CSTD devices
    - Procedures for containment, cleanup and disposal for breakage, spills, per federal and state regulations
    - Treatment for personnel with contact and inhalation exposure
- The organization will develop a list of drugs, including antineoplastic (chemotherapy) drugs, that are categorized as hazardous or having hazardous characteristics. Management of these drugs will follow the USEPA/RCRA standards for hazardous agents.
- Individuals preparing chemotherapy agents will do so in the area dedicated within the Pharmacy where access is restricted to authorized personnel only.
- Specialized compounding devices and equipment will be used for chemotherapy agents.
- Employees involved in compounding antineoplastics will wear gloves, gowns, head and shoe covers.

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
	PAGE: 3 OF: 5
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

- Masks may also be used if needed. This apparel is never to be reused and will be discarded after each use.
    - Two (2) pairs of powder disposable chemotherapy gloves, with the outer one covering the gown cuff, will be worn whenever there is a risk of exposure to hazardous drugs.
    - A disposable gown made of low-lint, low-permeability fabric, with a closed front, long sleeves and elastic or knit closed cuffs, will be worn.
    - A face shield will be worn whenever there is a risk of exposure to hazardous drugs and engineering controls are not available, to avoid splash incidents involving the eyes, nose or mouth.
- All work involving the mixture or compounding of antineoplastics will be performed in the biological safety cabinet (ventilated cabinet designed to protect workers and adjacent personnel from exposure) or a compounding aseptic containment isolator (CACI) (ISO Class 5) located in the main Pharmacy. Syringes and IV sets with "Luer-Lok" fittings will be used for preparing and administering chemotherapy drugs that are considered hazardous agents. All material ancillary to the dose will be discarded as chemotherapy waste in the appropriate container. Compounding of sterile doses should use modified aseptic technique, taking into account the air-flow parameters of the environmental containment and control devices. Agents requiring aseptic technique will be prepared in aseptic manner, with full protection of the drugs requiring asepsis.
- When additional protection is necessary due to hazardous agents, use closed system, drug transfer devices, glove bags and needle-less systems within the ventilated cabinet.
- Antineoplastic drugs shall be stored in the manufacturer's packaging until ready for use. These packages will be stored in the IV room on shelving designated for chemotherapy storage, and shall be stored separately from other inventory.
    - Storage of many hazardous drugs should be within a containment area, i.e., negative pressure room.
        - Sufficient exhaust ventilation should be at least 12 air exchanges per hour to dilute and remove airborne contaminants.

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
	PAGE: 4
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 5
	EFFECTIVE:NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

- All chemotherapy doses and waste shall be labeled with the words "Chemotherapy - Dispose of Properly", with all hazardous wastes and contaminated materials handled separately from other trash.
- Work areas will be decontaminated before and after each activity involving the use of hazardous drugs, and at the end of each shift.
- Assay of surface wipe samples shall be performed every six (6) months.
- In the event of direct contact with antineoplastic agents:
  - Immediately change the involved gloves or gown.
  - Immediately wash the affected skin area with soap and water; it should be examined by a physician as soon as possible.
  - For eye exposure, immediately flood the affected eye with water or eyewash designated for that purpose. Medical attention should be obtained immediately.
  - Refer to MSDS for treatment guidelines.
- Sprayback and spill control techniques and equipment will always be employed by Pharmacy staff.
- In the event of small (less than 5 mL) spills in the environmental containment device:
  - Cover and clean with absorbent gauze.
  - Dispose of all materials as chemotherapy waste.
- In the event of small spills outside of the hood:
  - Mark the area to prevent cross contamination and exposure.
  - Clean up with gloves, gown, mask and eye protection (provided in proprietary clean up kits).

SUBJECT: CHEMOTHERAPY HANDLING	REFERENCE #1013
	PAGE: 5 OF: 5
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

- In the event of large (greater than 5 mL, or greater than 5 gm) spills:
    - Contain the spill and refer to the MSDS and Safety Manual.
- All spill cleanup materials should be disposed of in a hazardous chemical waste container in accordance with USEPA/RCRA regulations regarding hazardous waste, not in a chemotherapy waste or biohazard container.
- Routine waste collection and disposal for other chemotherapy waste will be in accordance with Environmental Services policies and procedures for chemotherapy waste disposal
    - All chemotherapy waste will be placed in white chemotherapy waste containers and marked with the words "Chemotherapy - Dispose of Properly".

REFERENCES:

- NIOSH "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings", March 2004.
- OSHA standards: Hazard Communication Standard (29 CFR 1910.1200); Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450)
- OSHA technical manual guidelines "Controlling Occupational Exposure to Hazardous Drugs"
- USP General Chapter <797>, Pharmaceutical Compounding - Sterile Preparations

SUBJECT: CRITICAL SITES	REFERENCE #1020
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

DEFINITION:

Critical Site: Any opening which provides a conduit between a sterile ingredient and the surrounding environment, or any item that comes in direct contact with the sterile ingredient and environment (direct contact with air, moisture or touch contamination).

POLICY:

- This facility uses laminar airflow workbench (LAFW)
- Laminar airflow workbenches include:
    - Horizontal flow clean benches
- Barrier isolators are positive pressure systems that separate the external environment from the critical site.
- Certification of LAFWs and barrier isolators are conducted every six (6) months.
- LAFWs and barrier isolators provide appropriate critical site environment for sterile compounding.
- LAFWs and barrier isolators provide an ISO Class 5 environment.
- LAFWs shall have a visible pressure gauge. Compounding personnel will check the reading on the pressure gauge before compounding.
- LAFWs will be in clean rooms (buffer zone).

SUBJECT: CLEAN ROOM (BUFFER AREA)	REFERENCE #1021
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Access to the buffer area is restricted to staff who are assigned to the compounding area.
- Traffic in and out of the clean room will be kept at a minimum.
- Buffer area meets ISO Class 7
- Furniture, equipment and supplies that are in the clean room are dedicated to the clean room. Items will only be removed for servicing and/or preventive maintenance.
- Furniture, equipment and supplies shall be nonpermeable, non-shedding and resistant to disinfecting agents.
- Only the furniture, equipment and supplies needed for sterile compounding will be in the clean room.
- Pharmacy personnel will clean and disinfect all furniture, equipment and supplies with hospital-approved disinfectant before placement in the clean room.
- All supplies will be removed from their shipping cartons and wiped with 70% isopropyl alcohol.
- No food, drink, gum or candy is allowed in the clean room.
- All waste receptacles shall be below the level of the LAFW.
- Only non-shedding paper products may be brought into the clean room, i.e., no pencils, cardboard, paper towels or cotton items.
- Compounding personnel shall be able to access the clean room from the ante-area, hands-free.

SUBJECT: CLEAN ROOM (BUFFER AREA)	REFERENCE #1021
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

PHYSICAL ATTRIBUTES OF THE CLEAN ROOM:

- Ceiling, walls, floors, lighting fixtures, shelves, counters and all work surfaces will be made of non-shedding materials and be smooth and impervious. There will be no cracks or crevices where dirt, microorganisms and contaminants can accumulate.
- The area where the ceiling and the walls meet will be coved or caulked.
- All surfaces will be resistant to damage from disinfectants.
- Ceilings will be impervious and hydrophobic. The ceilings will be caulked to seal the ceilings to the support frames.
- Walls will be made of epoxy-coated gypsum board. Panels may be used for the walls if the panels are locked together and sealed.
- Floors will be of wide-sheet vinyl flooring.
- All opening in the walls or ceilings will be sealed.
- There are no sinks or drains in the clean room.

SUBJECT: PHYSICAL ENVIRONMENT REQUIREMENTS FOR STERILE COMPOUNDING	REFERENCE #1022
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Laminar airflow workbenches, biological safety cabinets or barrier isolators will be located in the clean room (buffer area).
- The clean room is the environment immediately surrounding the LAFWs.
- The air quality of the clean room shall be a minimum of ISO Class 7.
- The space beyond the clean room is the ante-area.
- Low-Risk And Medium-Risk CSPs:
  - Clean room - ISO Class 7 (minimum)
  - Beyond the clean room is a demarcation line or barrier that separates the clean room from the ante-area
- High-Risk CSPs:
  - Clean room - ISO Class 7 (minimum)
  - The clean room is physically separated from the ante-area
- Engineering will maintain the appropriate air conditioning and humidity leaves in the clean room and ante-area.

SUBJECT: ANTE-AREA	REFERENCE #1023
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The ante-area is the area beyond the clean room.
- ISO Class 8 environment for ante-areas.
- For low-risk and medium-risk compounding, the ante-area is separated from the clean room by a line of demarcation or physical barrier.
- For high-risk compounding, the ante-area is physically separated from the ante-area.
- Supplies will be removed from shipping cartons, cleaned and disinfected with 70% isopropyl alcohol and stored in the ante-area on a clean and disinfected cart.
- The ante-area contains a sink with a hands-free faucet and hand dryer for hand hygiene.
- Compounding personnel will don gown, masks, goggles, shoe and head covers in the ante-area.

SUBJECT: LAFWs OR BARRIER ISOLATORS	REFERENCE #1024
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- All sterile compounding shall be prepared under the laminar airflow hood using aseptic technique.
- LSFWs, BSCs, CAIs and CACIs shall be located in a restricted access ISO Class 7 buffer area.
- The blowers of LAFWs or barrier isolators will be kept on throughout the compounding session.
    - Blowers will remain on during interruptions of compounding sessions of less than eight (8) hours.
- Only one (1) pharmacy staff member may enter the clean room to turn on the blower and clean and disinfect the work surfaces.
    - The blower must be on for a minimum of 30 minutes before a compounding session takes place.

SUBJECT: LAMINAR AIRFLOW HOOD MAINTENANCE	REFERENCE #1025
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 03/01/2018
APPROVED BY: FLYNN LEW PHARM.D.	REVISED: 08/06/2021

POLICY:

The laminar airflow hood (LAFW) utilizing a HEPA filter will be used for all intravenous admixture activities within the Pharmacy Department.

PROCEDURE:

- The laminar airflow hood shall be turned on continuously except for filter changes and other required maintenance.
- Pre-filters will be changed every 6 months or more frequently if necessary due to working conditions. A log will be maintained documenting when the filters are changed.
- The laminar airflow hood shall be cleaned every shift and PRN with disinfectant solution. All surfaces should be cleaned adequately. Sterile non-shedding cloths used to clean hood surfaces shall be discarded after use.
- The laminar airflow hood shall have routine contract maintenance performed every six (6) months, or when the LAFW is relocated, to assure proper function of HEPA filters. Documentation of such maintenance will be maintained in the Pharmacy Department.
- Air sampling will be performed in areas most prone to contamination during compounding activities.
- Air quality sampling will be outsourced and volumetric air sampling be completed:
    - Every six months, at a minimum, for sterile compounding areas used for category 1 and category 2 preparations

SUBJECT: LAMINAR AIRFLOW HOOD MAINTENANCE	REFERENCE #1025
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 2 OF: 2
	EFFECTIVE: 03/01/2018
APPROVED BY: FLYNN LEW PHARM.D.	REVISED: 08/06/2021

- The laminar airflow hood shall be certified every six (6) months and as needed by an independent contractor.
    - The independent contractor will test and certify that the LAFW or barrier isolator is functioning correctly and meets the air quality requirement of ISO Class 5.

REFERENCE:

USP General Chapter <797>, Pharmaceutical Compounding - Sterile Preparations

SUBJECT: ENGINEERING CONTROL PERFORMANCE VERIFICATION	REFERENCE #1026
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Performance of LAFW, buffer area and ante-area shall be tested by a qualified person and certified at least every six (6) months and when the device or room is relocated or changed in any way.
- Performance Testing:
  - ISO Class 5:
    - Not more than 3,520 particles of 0.5 µm size and larger per cubic meter of air for any LAFW.
  - ISO Class 7:
    - Not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area
  - ISO Class 8:
    - Not more than 3,520,000 particles of 0.5 µm size and larger per cubic meter of air for any ante-area
- Certification shall be reviewed, documented and maintained.
- Prefilter shall be checked and replaced if necessary every 6 months by qualified person and logged.
- Any results found to be outside of the norm shall be reported to the Pharmacist-in-Charge.
- The Pharmacist-in-Charge shall take immediate action to solve the problem.

SUBJECT: PRESSURE DIFFERENTIAL MONITORING	REFERENCE #1027
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 12/04/19
APPROVED BY: FLYNN LEW	REVISED:

POLICY:

- A pressure gauge or velocity meter shall be used to monitor the pressure differential (or airflow) between the buffer area and the ante-area, and between the ante-area and the general environment.
- Results shall be logged for daily.
- Any discrepancies shall be reported immediately to the Pharmacy Director/designee.
- The Pharmacy Director shall review the log on a daily basis.

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SUBJECT: AIR QUALITY CHECKS	REFERENCE #1028
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 03/01/2018
APPROVED BY: FLYNN LEW PHARMD	REVISED: 01/14/2021

POLICY:

- Air quality testing will be completed for LAFW, clean room and ante-areas on a scheduled basis.
- Air quality checks for LAFW:
    - Every 6 months for compounding areas used for low-risk and medium-risk preparations by exposing agar plates performed by licensed pharmacy personnel or outsourced licensed certification entity.
- Air quality checks for clean room and ante-area (particulate air sampling)
- Air quality check records will be maintained by the Pharmacist-in-Charge or designee.
- Air quality checks may be performed by exposing agar plates to the environment.
- Air sampling shall be performed at locations compounding personnel deem most prone to contamination during compounding procedures.
- Agar Plates:
    - Remove covers of agar plates.
    - Place agar plates in designated areas.
    - Expose the agar plates to the environment for one (1) hour or more.

SUBJECT: AIR QUALITY CHECKS	REFERENCE #1028
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 03/01/2018
APPROVED BY: FLYNN LEW PHARMD	REVISED: 01/14/2021

- Collect the agar plates after exposure time has been completed.
- Cover the agar plates and incubate at the temperature and time period specified by the manufacturer of the agar plates (usually 26 to 30 degrees C for at least fourteen [14] days).
- Colonies of microorganisms are counted after incubation and reported as colony forming units (CFUs).

- The normal baseline CFU count over 14 days should be zero [0].
- Establishing a CFU baseline will help to identify an increasing trend of CFU counts.
- The Pharmacist-in-charge will determine a plan of action when any CFU count exceeds its respective action level.
  - Action levels are based on CFU data collected at each sampling location and trended over time (USP <797> has an Action Level Table to serve as a guideline).
- If pathogenic micro-organisms, such as gram-negative rods, molds, yeast, coagulase positive staphylococcus, are found, regardless of the CFU count, this situation shall be corrected immediately.
- An increase in CFU counts over time will warrant an evaluation of:
  - Cleaning procedures
  - Operational procedures
  - Air filtration efficiency
  - Procedures will be revised as necessary

SUBJECT: INFECTION CONTROL	REFERENCE #1029
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED: 11/21/15

PURPOSE:

- To assure appropriate compounded sterile preparation practices as they relate to infection prevention and control.
- Responsibilities of the Pharmacy Director:
  - Establish regulations for preparation of intravenous medications.
  - Assure the availability of adequate equipment to safely prepare intravenous fluids.
  - Assure that pharmaceutical preparations are sterile, properly packaged, labeled, stored and not outdated.
  - Certify the compounding skills of compounding staff.
  - Assist in the investigation of outbreaks of infection that may be the result of contaminated medications.
  - Assure that personnel health standards are maintained within the department.
  - Personnel who perform compounding procedures in ISO Class 5 and ISO Class 7 will not be permitted to perform their duties until the following are resolved:
    - Skin rash
    - Sunburn
    - Weeping sores
    - Conjunctivitis
    - Respirator infection
    - The Pharmacy Director and Employee Health will confer on these issues

SUBJECT: INFECTION CONTROL	REFERENCE #1029
	PAGE: 2 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED: 11/21/15

- Present policies and procedures to the Infection Control Committee.
- Personnel shall report potential toxic effects or drug reactions to the Pharmacy Director.

- Ante-Area:
  - Hand hygiene and the donning of appropriate garb are performed in the ante-area.

- Buffer Area/Clean Room Infection Control:
  - Traffic is kept to a minimum in the DCA in the clean room.
  - Supplies needed for an immediate compounding session will be wiped with 70% isopropyl alcohol before the item is brought into the clean room.
  - Items packaged in sealed pouches will be removed from the pouches before immediate introduction into the clean room. It is not necessary to wipe these items with 70% isopropyl alcohol.
  - Food, drink, candy and gum are not permitted in the ante-area, buffer areas or segregated compounding areas.
  - At the beginning of each shift and when spills occur, the surfaces of the direct compounding area are cleaned with purified water and then disinfected with 70% isopropyl alcohol with a disposable, non-shedding cloth.
  - Supplies will be gathered at the edge of the DCA. Supplies will then be disinfected with 70% isopropyl alcohol before being introduced into the aseptic work area.
  - All supplies are arranged in the DCA for maximum efficiency and to allow an uninterrupted path of HEPA-filtered air to bathe all critical sites during compounding.
  - Rubber stoppers of vials and the neck of ampules shall be disinfected with 70% isopropyl alcohol and allowed to dry for at least 10 seconds before withdrawing the contents with a sterile needle or spike.
  - Antiseptic hand cleansing with an alcohol-based surgical hand-scrub and the donning of sterile gloves is performed in the buffer area.

SUBJECT: INFECTION CONTROL	REFERENCE #1029
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DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED: 11/21/15

- Sterile, disinfected gloves do not remain sterile during compounding procedures. Compounding personnel must remember not to touch sterile edges of packaging, transfer devices, etc.

- All supplies and equipment will be stored in an environment that is free of moisture, excessive temperature fluctuations or contamination. Correct temperature, humidity and lighting will be maintained in the supply areas.

- Syringes and needles shall be directly discarded into red puncture-proof container and the needles shall not be cut or re-sheathed.

- See Critical Sites policy, LAFWs or Barrier Isolators policy, Cleaning and Disinfection of the Sterile Compounding Areas - Pharmacy Responsibilities policy, Cleaning of the Clean Room and Ante-Area - Environmental Services Responsibilities policy, Attire in the Clean Room policy, Hand Scrub policy, Aseptic Technique policy.

SUBJECT: DISPOSAL OF SHARPS	REFERENCE #1030
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

PURPOSE:

To prevent injury and exposure to bloodborne infections for personnel handling sharps, including needles, syringes and opened ampules of medication.

POLICY:

- All sharps, including hypodermic needles and syringes, and opened glass ampules of medicine will be disposed of into rigid, puncture resistant plastic sharps containers.
- Needles shall not be recapped or cut after use. This will prevent needle puncture injury and aerosolization of contents, per CDC recommendations.

PROCEDURE:

- After syringe/needle use, **DO NOT RECAP.**
- Slip needle through opening in top of plastic "sharps" container.
- Opened glass ampules will be handled carefully. All medication shall be removed from ampule and the ampule placed into contaminated sharps container.

PRECAUTIONARY MEASURES:

- Under no circumstances shall sharps be discarded into waste or trash containers.
- Bare needles will not be left on IV poles, instrument trays or any place that may pose a hazard to personnel, patients or visitors.
- **DO NOT RECAP NEEDLES.** This is the single most important cause of needle puncture injury.

SUBJECT: CLEANING AND DISINFECTING SOLUTIONS	REFERENCE #1031
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	
	EFFECTIVE: 03/01/2018
APPROVED BY: SHABANA YASMIN, PHARMD	REVISED: 03/19/2019

POLICY:

- The Pharmacy-in-charge will select the cleaning and disinfecting solutions to be used in the compounding areas.
- Only approved solutions shall be used. Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly
- Selection of cleaning and disinfecting solutions will be based on:
  - The most current literature
  - Microbicidal activity
  - Compatibility
  - Effectiveness
  - Any toxic residues
  - Inactivation by organic matter
  - Shelf life

SUBJECT: CLEANING SUPPLIES	REFERENCE #1032
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/2018

POLICY:

- All cleaning supplies, i.e., wipes, cloths, mops, shall be made of non-shedding materials.
- All cleaning supplies for the clean room and ante-area are dedicated to the clean room and ante-area.
- Floor mops will be cleaned and disinfected after each use, per manufacturer's instructions.

SUBJECT: CLEANING AND DISINFECTION OF THE STERILE COMPOUNDING AREAS - PHARMACY RESPONSIBILITIES	REFERENCE #1033
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/2018

POLICY:

- Pharmacists and/or technicians will clean and disinfect the direct compounding area(s) (DCA - LAFW):
    - At the beginning of each shift
    - Before each batch
    - Every 30 minutes during continuous compounding of individual CSPs
    - After spills
        - When liquids are spilled, the DCA shall be cleaned with USP purified water to remove water-soluble residues, then disinfect the surface.
    - When contamination is known or suspected
- General cleaning of the buffer areas and ante-areas is also to be performed on a daily basis.

PROCEDURE:

- DCA Cleaning:
    -
    - Wipe all areas with a clean non-shedding cloth and purified water, followed by sterile 70% Isopropyl Alcohol.
        - Wipes are dedicated to DCA cleaning.
    - Wipe all compounding areas with a sterile 70% Isopropyl Alcohol. Allow time for the antimicrobial properties of the sanitizing agent to work (exposure time).
    - Wipe hood exteriors, including tops and bases with disinfectant weekly.

SUBJECT: CLEANING AND DISINFECTION OF THE STERILE COMPOUNDING AREAS - PHARMACY RESPONSIBILITIES	REFERENCE #1033
	PAGE: 2
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/2018

- Clean Area, Ante-Area Cleaning:
  - Clean all work surfaces (countertops, carts, containers, shelves) in the clean room at the beginning of each shift.
  - Storage shelves will be emptied and cleaned and disinfected weekly and as needed.
  - Waste receptacles shall be removed from the clean room and then emptied every shift.
  - Floors are cleaned by mopping daily when there are no aseptic operations in place.
  - Mops are to be used in the clean room before use in the ante-area.
  - Walls, doors, glass and ceilings shall be cleaned weekly.
  - All cleaning activities will be recorded on the appropriate log sheet (See Attachment H and Attachment I).

SUBJECT: CLEANING OF THE CLEAN ROOM AND ANTE-AREA – PHARMACY STAFF RESPONSIBILITIES	REFERENCE #1034
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/18

POLICY:

- Pharmacy IV staff assigned to the Pharmacy Department will damp mop the floor in the clean room on a daily basis.
- Pharmacy IV staff will perform hand hygiene and don gown, shoe and head covers (available in the ante-area) before entering the clean room to mop the floor.
- Cleaning of the ante-area and clean room will be completed when there are no compounding activities being performed.
- The ante-area will be cleaned by Pharmacy IV staff.

PROCEDURE:

- Pharmacy IV staff will damp mop the ante-area floor on a daily basis.
- The same mop may be used for the clean room and ante-area. If using the same mop, ALWAYS mop from the clean room to the ante-area. Place wet floor signs prior to mopping.
- Storage shelves and bins are emptied and cleaned once per week.
- Empty all waste containers. The waste containers will be wiped out with the approved cleaning and disinfecting solutions. Replace bag liners.
- Clean sinks, soap dispensers and hand dryers with an approved cleaning agent and wipe dry, daily.

SUBJECT: CLEANING OF THE CLEAN ROOM AND ANTE-AREA – PHARMACY STAFF RESPONSIBILITIES	REFERENCE #1034
	PAGE: 2
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/18

- Walls are cleaned monthly and as needed.
- Surfaces of carts are wiped clean.
- All cleaning activities will be recorded on the appropriate log sheet (See Attachment H and Attachment I).
- See Cleaning and Disinfecting Solutions policy and Cleaning Supplies policy (Reference section #1031 and #1032).

SUBJECT: TEMPERATURE MONITORING	REFERENCE #1034B
	PAGE: 1
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 1
	EFFECTIVE: 11/01/2018
APPROVED BY: RENA CHARCHIAN	REVISED: 11/01/2018

POLICY:

Temperatures within the identified range will be maintained and monitored within the pharmacy on a daily basis for the following areas:

- Pharmacy room temperature: 20-25°C
- Clean room temperature: ≤20°C
- Refrigerator temperature: 2-8°C
- Incubator temperature: 30-35°C

PROCEDURE:

- The pharmacy staff will be responsible for monitoring and recording the temperatures at least daily for the general pharmacy dispensing area, the refrigerators, the clean room and the incubator (See Attachment I).

- If any staff member notes that temperatures fall outside of the acceptable temperature range at any time, the Pharmacist-In -Charge and Operations Manager will be informed immediately so that measures can be implemented to bring the affected area or device back into compliance.

- The Pharmacist-In-Charge, Operations Manager and IV Supervisor Pharmacist/Technician will periodically review the temperature logs for completeness and accuracy to assure that appropriate storage temperatures are being maintained.

- Temperature logs should be retained at least 3 years.

SUBJECT: ATTIRE IN THE BUFFER AREA (CLEAN ROOM)	REFERENCE #1035
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

PURPOSE:

Attire in the buffer area or segregated compounding area provides a barrier between personnel and the ingredients and devices used when performing sterile compounding procedures.

POLICY:

- All personnel entering the clean room/buffer area shall be in clean room attire.
- Clean room attire consists of (to be put on in this order):
  - Non-shedding shoe covers:
    - Shoe covers are removed and disposed of when leaving the clean room.
  - Non-shedding head and facial covers:
    - The head cover/facial cover should confine the hair.
    - Head covers/facial covers are removed and disposed of when leaving the clean room.
  - Face mask/eyeshields
    - Used when working with hazardous drugs and other irritants
  - Non-shedding knee-length gowns/coveralls
    - Gowns/coveralls shall fit snugly at the wrist, shall be closed in the front, and are enclosed at the neck

      Note: Gown is put on after the initial hand scrub in the ante-area.

SUBJECT: ATTIRE IN THE BUFFER AREA (CLEAN ROOM)	REFERENCE #1035
	PAGE: 2 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- Gloves:
  - Gloves shall be sterile and powder-free.
  - When compounding procedures are performed over a long period of time and when non-sterile surfaces are touched, compounding personnel will periodically disinfect gloves with 70% isopropyl alcohol.
  - Replace gloves if they have been torn, punctured or otherwise lose their ability to function as a barrier.

  Note: Hand hygiene is performed before putting on gloves. See Hand Scrub policy and procedure.

- Face Masks:
  - Masks shall cover the nose and mouth, and shall be discarded whenever removed.
  - Masks will be put on immediately before performing a procedure in the DCA.
  - If using a barrier isolator or vertical flow LAFW with a transparent shield, masks are not necessary, but head and facial hair will be covered.

- Compounding personnel will remove all jewelry, from hands and arms, and other visible jewelry or piercings, before entering the clean room.
- Compounding personnel will remove all make-up before entering the clean room.
- Staff working in the sterile compounding environment are prohibited from wearing artificial nails or extenders.
- Fingernails should be kept short and well maintained.

SUBJECT: ATTIRE IN THE BUFFER AREA (CLEAN ROOM)	REFERENCE #1035
	PAGE: 3 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- Compounding personnel who must leave the clean room may remove their gown at the entrance of the clean room and hang it inside out in an appropriate area of the ante-area, to be put on again when entering the clean room. This may only be done during the same shift.
    - Head and shoe covers, masks and gloves must be removed and discarded.
    - New head and shoe covers, masks and gloves must be donned before entering the clean room.
- When high-risk compounding procedures are being performed, gowns/coveralls may not be worn again once leaving the clean room.
- Clean room attire worn or taken outside of the ante-area may not be used in the clean room.

SUBJECT: HAND SCRUB	REFERENCE #1036
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- All compounding personnel must properly complete a hand scrub before entering the clean room.
- Hand scrub is performed outside the ante-area at a sink that has a hands-free faucet.
- Air dryer or disposable non-shedding towels will be used to dry hands and arms.

PROCEDURE:

- Ante-Area:
  - Remove all jewelry from hands and forearms.
  - Fingernails should be kept short and well maintained.
  - Hand and forearms must be free of rashes, sunburn and breaks in skin integrity.
  - Hand scrub is performed before putting on shoe covers, head/facial covers, face mask.
  - Preparation:
    - Adjust water temperature
    - Keep arms level and well away from body, with hands above elbows for duration of scrub
    - Clean underneath fingernails, using a nail cleaner, under running warm water

SUBJECT: HAND SCRUB	REFERENCE #1036
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- Scrub:
  - Wet hands and forearms
  - Apply soap to hands and arm
  - Wash from fingertips to three (3) inches above elbows, for at least 30 seconds
  - Wash/scrub all four (4) sides of each finger as efficiently as possible
  - Rinse hands and arms thoroughly
  - Turn off water using hands-free faucet
  - Dry hands and arms with air dryer or non-shedding disposable towel

- Buffer Area:
  - Hands shall be washed again, after donning gown, head and shoe covers, but before donning sterile gloves.
  - Waterless alcohol-based surgical handscrub shall be used. Follow manufacturer's instructions for application.
  - Allow hands to dry thoroughly before putting on gloves.

SUBJECT: ASEPTIC TECHNIQUE	REFERENCE #1037
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

DEFINITIONS:

- Aseptic technique is a method to eliminate contamination, germs or infection. A method of working while maintaining a sterile area by awarding contact with anything which is not sterile.
    - Sterile: Absence of all microorganisms including bacterial, viruses and spores.
    - Sterilization: The process of killing or inactivating all microorganisms.
    - Disinfection: Any process which renders inanimate objects free of pathogenic bacteria.
    - Contamination: Introduction of microorganisms to a sterile solution, device, etc.

POLICY:

- Compounding staff receive initial training in aseptic techniques before beginning compounding responsibilities.
- Aseptic technique training shall be ongoing.
- Aseptic technique competency of compounding staff shall be assessed according to risk level of CSPs they are compounding.

PRINCIPLES OF ASEPSIS:

- If in doubt about the sterility of any item, consider it unsterile.
- The edge of anything that encloses sterile contents is not considered sterile.
- Moisture may cause contamination.
- Gloved hands must be kept at waist level or above.

SUBJECT: ASEPTIC TECHNIQUE	REFERENCE #1037
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- All prepackaged sterile ingredients and devices will be inspected by compounding personnel for damage that includes:
  - Holes or torn wrappers
  - Security tapes that have been tampered with or removed
  - Broken seals in peel pouches
  - Items dropped that are wrapped or in peel pouches
  - Exposure to a contaminated or unsafe environment
  - Exposure to any type of moisture
  - Check expiration date
- If any of the above is found, ingredients/devices will be considered NOT sterile.

SUBJECT: INGREDIENTS	REFERENCE #1038
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Compounding personnel will verify the correct identity and quality of ingredients of CSPs through:
  - Vendors' labels
  - Certificates of analysis
  - Direct chemical analysis
  - Knowledge of appropriate storage conditions for the ingredients
- All labels of CSPs must have correct names, concentration of ingredients, total volume, beyond-use dating, route of administration and condition of storage.
- Records specific to compounding must be verified with original order for accuracy.

SUBJECT: STERILE INGREDIENTS AND COMPONENTS	REFERENCE #1039
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:05/04/09
APPROVED BY: SHABANA YASMIN	REVISED: 11/21/15

POLICY:

- Sterile Ingredients and components are purchased from licensed warehouse, distributor or manufacturers only.
- Compounding personnel shall inspect sterile ingredients, containers and devices before use for defects in packaging and unexpected appearance of the item. All ingredients and components must be sterile and free of defects and suitable for intended use.
- If sterility of an ingredient or component is ever in doubt, do not use that item.

SUBJECT: NON-STERILE INGREDIENTS AND COMPONENTS (HIGH-RISK)	REFERENCE #1040
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Compounding activities that use non-sterile ingredients and components will be considered high-risk level CSPs.
- Non-sterile active ingredients/substances will preferably be official USP or NF articles.
    - If unofficial ingredients/substances are used, there must be a certificate of analysis provided by the supplier of the ingredients/substances to attest identity, quality and purity.
- Compounding personnel will visually inspect the ingredients/substances and the packaging before compounding. Visual inspection will include:
    - Package integrity, i.e., holes, tears
    - Presence of loose cap
    - Package not closed securely
    - Expected appearance of the ingredient substance
    - Aroma of the ingredient substance
    - Texture of the ingredient substance
- All ingredients/substances will be stored according to the recommendations of monographs or suppliers.
- The date of receipt will be marked on each ingredient package received at the Pharmacy.
- If an ingredient does not have an expiration date declared by the supplier, that ingredient will not be used after one (1) year in the Pharmacy.

SUBJECT: COMPOUNDING EQUIPMENT MAINTENANCE	REFERENCE #1041
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED: 11/23/2015

PURPOSE:

To assure equipment/apparatus/devices used for compounding activities perform properly and safely, and that personnel are trained in the operation and maintenance of the equipment/ apparatus/devices used for compounding.

POLICY:

- The cleaning, sterilization, maintenance, calibration and repair of all compounding equipment is performed according to the manufacturers' recommendations.
- Routine maintenance will take place every month. All compounding equipment is inspected for operational integrity by compounding personnel, prior to each use and logged.
- Incubator, Refrigerator and Freezers are cleaned monthly.
- Temperature logs are maintained in the IV department and reviewed monthly.
- Equipment is to be removed from service, if needed repair or malfunction is evident. The Biomedical Engineering Department or service provider will be notified to repair equipment.
- Equipment calibration, maintenance reports and repair reports will be maintained by the Pharmacy-in-charge.

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SUBJECT: AUTOMATED COMPOUNDING DEVICES (ACDs)	REFERENCE #1042
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: NOT IN EFFECT
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Pharmacy personnel will perform daily calibrations and accuracy assessments of the automated compounding devices.
- Accuracy assessments will be documented and maintained in the Pharmacy Department
- The Pharmacy Director will keep a daily record of accuracy assessments and review the results over time. This review must be conducted at weekly intervals to avoid cumulative errors over time. The precision of the ACDs shall be determined on the basis of variations over time of the results of accuracy testing.
- Routine daily maintenance is performed on the parenteral nutrition compounding machine in the main pharmacy. Daily, the tubing sets and the solutions are changed and the device is calibrated according to the manufacturer's specifications on the large volume compounder and the electrolyte compounder. These actions are documented on a daily log by the Pharmacy Technician and the Pharmacist. The accuracy of solution placement is verified by the Pharmacist initially and with all changes/refills.

SUBJECT: FINISHED PREPARATION RELEASE CHECKS AND TESTS	REFERENCE #1043
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

CSPs will be inspected, before dispensing, by compounding personnel other than the person who performed the compounding (double-check system)

PROCEDURE:

- Inspection of CSPs includes:
  - Visual inspection for particulates and/or cloudiness. The CSP will be examined against a lighted white or black background, or both.
  - Verification of prescription orders with the written compound record (preparation records).
  - Verification of ingredients used, including correct amounts and concentrations.
  - Verification of final fill amounts
  - Verification of aseptic manipulations and sterilization
  - Package integrity; any leakage observed
  - Visual inspection of syringes and additive containers used
  - Correct and complete label:
    - Name of patient
    - Patient location
    - Correct names, amounts and concentrations of the ingredients
    - Total volume
    - Preparation date

SUBJECT: FINISHED PREPARATION RELEASE CHECKS AND TESTS	REFERENCE #1043
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- Beyond-use date
- Route of administration
- Storage requirements
- Route of administration
- Infusion rate when applicable
- The initials of the compounding personnel
- Labels for CSPs must be clear, consistent, legible and in compliance with state and federal regulations

- CSPs with visual defects will be immediately discarded.
- When the identity and concentrations of ingredients cannot be verified, samples of the CSPs will be assayed.
- CSPs that are not immediately dispensed will be stored according to procedure.
  - CSPs that are stored, will again be inspected before the CSPs are dispensed.

NOTE:

This double-check system must meet your state's regulations.

SUBJECT: STERILITY AND BACTERIAL ENDOTOXIN TESTING FOR HIGH-RISK LEVEL CSPs	REFERENCE #1044
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The following high-risk level CSPs that are administered into the vascular and central nervous systems will be subjected to sterility testing and bacterial endotoxin testing before they are dispensed or administered:
  - Prepared in groups of 25 or more identical individual single-dose packages
  - Multiple-dose vials for administration to multiple patients
  - CSPs that were exposed to temperatures of 2 to 8 degrees C for longer than 12 hours before they are sterilized
  - CSPs that were exposed to temperatures warmer than 8 degrees C for six (6) hours or longer before they are sterilized
- The membrane filtration method will be used to check sterility.
- High-risk level CSPs that undergo sterility testing will be held in quarantine until results of the sterility testing are known.
- In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP must not exceed the USP endotoxins limit (Bacterial Endotoxins Test <85>).
- All positive sterility and bacterial endotoxin tests mandate a thorough investigation of procedures and environmental controls to identify the source of contamination. A plan to correct those processes identified must be developed and implemented.

REFERENCES:

- Sterility Tests <71>
- Bacterial Endotoxins Test <85>

SUBJECT: STORAGE	REFERENCE #1045
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- All ingredients and CSPs will be stored according to the conditions stated on the label of ingredient products and finished CSPs.

- CSPs exposed to temperatures warmer than the warmest labeled limit, or to temperatures greater than 40 degrees C for four (4) hours or more, will be discarded unless direct assay confirms stability of the CSP.

SUBJECT: REFRIGERATED DRUG STORAGE	REFERENCE #1046
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

All refrigerated drug storage areas will be inspected daily to ensure compliance with drug storage standards.

DEFINITIONS:

- Refrigerator temperature range: 2 to 8 degrees C
- Room temperature range: 20 to 25 degrees C
- Freezer temperature range: -25 to -10 degrees C
- Incubator temperature range: 30 to 35 degrees C
- Suitable temperature recording devices include a calibrated continuous recording device or an NBS calibrated thermometer with alarms

PROCEDURE:

- Drug storage areas (refrigerators and freezers) will be inspected daily by the Pharmacist. A daily record log of temperature readings will be maintained on the outside door of the refrigerator.
    - If temperature varies outside the normal range the Pharmacist will attempt an adjustment of the temperature dial and re-evaluate in two (2) hours.
    - If unsuccessful the Pharmacist will notify the Engineering Department to fix the refrigerator.
    - In such a case, all drugs will be removed and stored elsewhere until repairs are completed. The nonfunctioning refrigerator/freezer will be clearly marked as needing repair and not to be used.

SUBJECT: REFRIGERATED DRUG STORAGE	REFERENCE #1046
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 2 OF: 2
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- Pharmacy personnel will also monitor temperatures when placing and removing items from the refrigerator/freezer. The Pharmacy freezer will be fitted with a continuous monitoring temperature gauge and alarm.
    - In the event of variance from normal temperature range, the Pharmacist will be consulted immediately to determine the disposition of drugs.

SUBJECT: BEYOND USE DATES	REFERENCE #1047
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 06/04/20
APPROVED BY: FLYNN LEW PHARM.D.	REVISED: 06/22/23

POLICY:

A. Assigning beyond-use dates (BUD) for CSPs is based on parameters that may affect quality, and the achievement and maintenance of sterility.

B. Determining BUD for CSP

1. Quality may be affected by the following parameters:

   a. Chemical and physical stability properties of the drug and or its formulation

   b. Materials of composition of the container closure system and compatibility of the container closure system with the final preparation (e.g., leachable, interactions, adsorption, and storage conditions).

2.Sterility achievement and maintenance may be affected by the following factors:

   a. Conditions of the environment in which the CSP is prepared.
   b. Aseptic processing and sterilization method
   c. Starting components (e.g., sterile vs nonsterile ingredients)
   d. Whether or not sterility testing is performed
   e. Storage conditions (e.g., packaging and temperature).

3.Each CSP formula record shall note the appropriate storage conditions and the BUD assigned.

4. The BUD must not exceed the shortest remaining expiration date of any of the commercially available starting components.

SUBJECT: BEYOND USE DATES	REFERENCE #1047
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 06/04/20
APPROVED BY: FLYNN LEW PHARM.D.	REVISED: 06/22/23

BEYOND-USE DATING FOR STERILE COMPOUNDED DRUG PREPARATIONS*

Compounding Environment	Sterility Testing Performed and Passed	Controlled Room Temperature (20°-25°C)	Refrigerated Storage (2-8°C)	Freezer Storage (-25°C to -10°C)
ISO Class 5 PEC in ISO Class 7 cleanroom (Category 2)	No	4 days	10 days	45 days
ISO Class 5 PEC in ISO Class 7 cleanroom (Category 2)	Yes	30 days	45 days	60 days

- *Prepared from only sterile starting components.*

SUBJECT: PACKAGING, HANDLING AND TRANSPORT	REFERENCE #1048
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The Pharmacy Director will maintain, continuously evaluate and revise, as needed, procedures for the safe packaging, handling and transport of each CSP prepared by the department to ensure maintenance of physical integrity, sterility and stability of CSPs.
- Procedures will be specific to safety mechanisms, special packaging, special inserts, foam padding, sealed plastic bags, tamper-proof closures and seals, etc.
- Safety mechanisms will be determined for each CSP prepared by the Pharmacy Department in relationship to mode of transfer and stability of the CSP.
- Special consideration shall be given to chemotoxic and other hazardous CSPs. Package integrity must be maintained to protect healthcare personnel from contact exposure.

SUBJECT: PACKING AND TRANSPORTING CSPs TO OUTSIDE LOCATIONS	REFERENCE #1049
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE:05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- CSPs distributed to locations outside of the compounding facility will be appropriately packaged and transported to the receiving customer.
- Packing materials and containers will be selected based on the specifications of the ingredients of the CSP and Pharmacist's knowledge to ensure the physical integrity, sterility and stability of the CSP.
- Pharmacy personnel will include instructions for the customer to safely open and unpack the CSP.
- Pharmacy personnel must verify with transporters that storage temperatures are met during transit, and handling and exposure instructions are followed.

SUBJECT: STORAGE OF CSPs OUTSIDE OF THE COMPOUNDING PHARMACY	REFERENCE #1050
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 1 OF: 1
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The compounding pharmacy that ships CSPs to patients shall ensure that the CSP label includes (clearly visible):
  - Beyond-use date
  - Storage instructions
  - Instructions for the disposal of out-of-date CSPs
- The compounding pharmacy shall verify that the patient has a properly functioning refrigerator/freezer if this is the storage requirement for the CSP.

SUBJECT: CSP STORAGE ON PATIENT CARE UNITS	REFERENCE #1051
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: NOT IN USE
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Nursing staff will immediately store CSPs, upon arrival on the patient care unit, according to the storage requirements on the label of the CSP.
- CSPs will be stored in the medication refrigerator only.
- Refrigeration temperature will be monitored and logged on a daily basis.
- Refrigeration temperature will be between 2 and 8 degrees C.

SUBJECT: ADMINISTRATION OF CSPs - NURSING	REFERENCE #1052
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Nursing staff will follow policies and procedures in the Nursing Policy and Procedure Manual for the administration of CSPs.
- Policies and procedures should include:
  - Visual inspection of the CSP and its packaging
  - Hand hygiene
  - Aseptic technique
  - Site care
  - Change of administration sets
  - Infusion pumps
  - Implantable infusion ports
  - In-line filtration
- The licensed nurse shall not administer any CSP that is cloudy and/or contains particulates, or if the integrity of the packaging has been compromised.
- The licensed nurse shall immediately notify the Pharmacy of any problem and send the CSP back to the Pharmacy immediately.

SUBJECT: RE-DISPENSING OF CSPs	REFERENCE #1053
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE:
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The Pharmacy Department has sole discretion whether CSPs, returned from patient care units, may be used for another patient.
- The CSP may be re-dispensed only if the Pharmacy can ensure the quality of the CSP and the beyond-use date has not been reached.

SUBJECT: PATIENT/CAREGIVER EDUCATION	REFERENCE #1054
	PAGE: 1 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- The Pharmacy Department, in coordination with nursing and medical staff, will instruct the patient/caregiver regarding the safe storage, handling and administration of CSPs.
- Instruction will include:
  - Why the CSP has been prescribed
    - Goals and expected outcomes
  - Potential side effects
  - Inspection of the CSP and supplies/equipment when received
    - Packaging is intact
    - What to do if the integrity of the package has been compromised
    - What to do if there is a problem with administration devices
  - Proper storage of the CSP
  - How to read the label on the CSP
    - Always check the label of the CSP before administration for:
      - Right drug
      - Right dose
      - Right patient
      - Right route of administration
      - Right time of administration

SUBJECT: PATIENT/CAREGIVER EDUCATION	REFERENCE #1054
	PAGE: 2 OF: 2
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- How to handle the CSP and associated supplies/equipment
- Inspect the CSP immediately before administration for particulates, cloudiness, leakage and discoloration
- Cleaning of the preparation area in the home
- Hand hygiene
- Aseptic technique
- The administration and discontinuation of the CSP
- Care of catheters, catheter site, dressing and patency
- Recognize IV therapy complications
- How to respond to emergency situations, i.e., equipment malfunction, catheter breakage, disconnect of IV tubing
  - Know who to call in an emergency
- The handling of biohazardous waste and proper disposal
- Sharps disposal
- Who to call with any questions, concerns or problems

- Educational materials shall include written instructions and checklists.
- Hands-on demonstration and practice shall be completed by the patient/caregiver before administering CSPs.

PATIENT/CAREGIVER CSP COMPETENCE ASSESSMENT

Name: _____ Date: _____

Instructor: _____

Skills	Date	Demonstrated	Practiced	Comments/Suggestions
Hand hygiene				
Aseptic technique				
Administration of CSP				
Discontinuation of CSP				
Care of catheter				
Care of catheter site				
Care of dressing				
Recognizing IV therapy complications				
What to do or who to call in an emergency				
Biohazardous waste				
Sharps disposal				
Inspection of CSP and supplies/ equipment upon arrival				
Proper storage of the CSP				
Reading the label:				
Correct patient				
Correct drug				
Correct dose				
Correct route of administration				
Correct administration time				
Inspection of CSP before administration				
Operation of supplies and equipment				
Goals of CSP				
Potential side effects of the CSP				
Who to call with questions/ concerns/problems				

SUBJECT: PATIENT MONITORING	REFERENCE #1056
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

POLICY:

- Patients treated with CSPs will be monitored by the Pharmacy Department according to accepted standards of practice and the rules and regulations of the California state board of pharmacy.

- The Pharmacy Department shall notify the FDA and United States Pharmacopoeia (USP) to report adverse event reporting and product defects.

- See Adverse Drug Reaction Reporting policy, Adverse Drug Reaction Reporting Form, Potential Adverse Drug Reaction Form, Adverse Drug Report Form.

SUBJECT: ADVERSE DRUG EVENTS REPORTING	REFERENCE #1057
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

PURPOSE:

To provide guidance on the reporting and review of Adverse Drug Events (ADEs) which includes adverse drug reactions and medication occurrences.

DEFINITION:

A. Adverse Drug Reaction
   a. Defined by ASHP (American Society of Heath-System Pharmacists), an adverse drug reaction is any unexpected, unintended, undesired, or excessive response to a drug that requires any of the following:
      i. Discontinuing, changing, or modifying the drug or dose
      ii. Hospital admission, prolonged stay, or supportive care or treatment
      iii. Significantly complicates, diagnosis, negatively affects prognosis, or results in temporary or permanent harm, disability, or death.

B. Medication Occurrence
   a. Defined as an error in prescribing, verifying, dispensing, preparing, documenting, or monitoring a medication.

REPORTING:

A. Pharmacy Quality Assurance Program documentation

   a. Documentation of adverse drug reactions and medication occurrences
      i. Each documented report is reviewed and investigated.
      ii. Aggregate monthly quality assurance are periodically reviewed and trended
   b. Pharmacy personnel shall be informed of changes to existing pharmacy policy, procedures, or processes because of the quality assurance program.

B. Food and Drug Administration (FDA)
   a. FDA MedWatch program
      i. Program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.
   b. Reporting methods
      i. Completing FORM FDA 3500B
      ii. Phone: 1-800-FDA-1088
      iii. Fax: 1-800-FDA-0178

ADVERSE DRUG REACTION REPORTING FORM

REPORT ANY REACTION OR INCIDENCE THAT MAY BE A DETRIMENTAL RESPONSE TO A MEDICATION WHICH IS UNDESIRED, UNINTENDED OR UNEXPECTED IN DOSES ACCEPTED IN THE MEDICAL PRACTICE.

Patient Name: _____ MR#: _____

Date of Reaction: _____ Known Allergies/Sensitivities: _____

Suspected Drug: _____ Start Date: _____

Concurrent Drugs: _____

Describe Reactions: _____

Circle all that apply:

GI	SKIN	CV	CNS	LABS	OTHER
Nausea	Rash	Hypertension	Headache	LFTs	Short of Breath
Vomiting	Itching	Hypotension	Confusion	Scr/BUN	Wheezing
Diarrhea	Flushing	Chest Pain	Anxiety	Neutropenia	Fever
Constipation	Swelling	Arrhythmias	Sedation	Anemia	Chills
GI Upset	Phlebitis	Bradycardia	Depression	Electrolyte	Seizures
GI Pain	Erythema	Tachycardia	Malaise		Shock

Was the Physician Notified: ❑ Yes ❑ No

Treatment of reaction: (Circle or list drugs prescribed or actions taken.)

Discontinued drug	Epinephrine	Kayexalate	Benztropine	Vancomycin PO
Decrease dose	Hydroxyzine	Naloxone	Physostigmine	Other: _____
Obtain drug level	Insulin	Phytonadione	Blood Products	_____
Diphenhydramine	Digibind	Protamine	Romazicon	_____
Dextrose	Glucagon	Meclizine	Steroids	_____

PREVENTABILITY ASSESSMENT

1. Was the drug involved in the ADR inappropriate for the patient's clinical condition?
2. Were the dose, route and frequency of administration appropriate for the patient's age, weight, organ function and disease state?
3. If the reaction was due to a drug allergy, was this allergy previously documented?
   ❑ Admitting orders ❑ Pharmacy computer ❑ Nursing Kardex
4. Were appropriate therapeutic drug monitoring or other laboratory tests performed, which may have predicted this reaction? (include toxic serum levels)
5. Reaction involved a drug-drug, drug-food or drug-lab interaction.

SEVERITY ASSESSMENT

1. An ADR occurred but required no change in treatment with the suspected drug.
2. The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed. No antidote or other treatment required. No increase in length of stay.
3. The ADR required that treatment with the suspected drug be held, discontinued or otherwise changed **AND/OR** an antidote or other treatment was required.
4. Serious ADR, but drug's benefits outweigh the adverse effects; drug is continued.
5. The ADR was the reason for admission.
6. The ADR treatment required intensive medical care. Increase length of stay.
7. The ADR caused permanent harm to the patient.
8. The ADR directly or indirectly led to the death of the patient.

THESE TYPES OF ADR ARE REPORTABLE TO THE FDA - MED WATCH

1. The suspected drug has been on the market for less than two (2) years.
2. The reaction is not listed in the package insert.
3. The reaction is attributed to an investigational drug.
4. The reaction contributed to the death of the patient.
5. The reaction was life-threatening or permanently disabling.

This information will remain confidential. Upon completion of the form, return to the _____ Department.

Completed by: _____ Date: _____

POTENTIAL ADVERSE DRUG REACTION FORM

THIS IS NOT A PERMANENT CHART FORM

Reaction Date: _____ Time of Reaction: _____

Patient Name: _____ MR#: _____

Location Where Reaction Occurred/Noted: _____

Suspected Cause: _____

Time Agent Administered: _____

Has patient ever received this agent before? ❑ Yes ❑ No ❑ N/A

Any past reaction noted? ❑ Yes ❑ No ❑ N/A

Manifestation of Past Reaction: _____

Known Allergies/Sensitivities: _____

CHECKLIST: (check appropriate symptoms/signs)

NEURO:	RESPIRATORY:	RENAL:	GI:
❑ Dizziness ❑ Confusion ❑ Paresthesia (incl. location: _____) ❑ Tingling (incl. location: _____) ❑ Change in Consciousness ❑ Tinnitus ❑ Hearing Acuity ❑ Fever ❑ Chills	❑ Dyspnea (rate) _____ ❑ Tachypnea (rate) _____ ❑ Shallow, slow ❑ Orthopnea ❑ Bronchospasm	❑ Hematuria ❑ Oliguria ❑ Anuria **CV:** ❑ Tachycardia ❑ Hypotension ❑ Hypertension ❑ Arrest ❑ Arrhythmias	❑ Nausea ❑ Vomiting ❑ Diarrhea ❑ Constipation ❑ Melena

SKIN:

❑ Rash site(s) _____
Type _____
❑ Alopecia
❑ Sloughing-necrosis

❑ Other _____
❑ Joint Pain (incl. location: _____)
❑ Edema (incl. location: _____)

Describe Reaction: (chronological sequence if possible) _____

Describe Therapy or Treatment Initiated: _____

Response to Treatment/Outcome of Incident: _____

Completed by: _____ Date: _____ Time: _____

Forward original to Pharmacy Department and attach copies to chart.

ADVERSE DRUG REPORT

Date: _____

Date Occurred	Medical Record #	Drug Involved	Severity Level	Prevent Level	Reported Patient Reaction/Symptoms	Treatment Ordered	Patient Outcome
List date first symptoms noted	List patient medical record #	List medication felt to be responsible	List levels as below (levels may be added)	List levels as below (levels may be added)	List noted patient symptoms, including lab values if appropriate	List any treatment ordered including stop orders for drugs	List patient condition after revision in Rx or treatment
Example:							
1/1/_____	#123456	Aminophylline	3 + 5	7	Tachycardia, nausea, tremor, Theophylline level 43.6, (one level obtained, 1/1/_____)	Aminophylline drip discontinued, compazine ordered	1/3/_____, Theo. level 14.1, HR = NSR, no nausea

Severity (S) Levels:

1. No action necessary, reaction minor
2. Change Rx, no treatment necessary
3. Change Rx, treatment instituted
4. Change Rx, provide Tx, requires admission or longer LOS
5. Change Rx, provide Tx, requires transfer to higher acuity unit (ICU/CCU)
6. Change Rx, provide Tx, results in irreversible harm/injury
7. Results in death

Preventability (P) Levels:

1. Unpreventable, Rx appropriate for Dx
2. Possibly preventable, different Rx could be ordered
3. Possibly preventable, drug-drug interaction noted
4. Possibly preventable, food-drug interaction noted
5. Preventable, documented patient allergy
6. Preventable, drug known to cause toxicity - no levels obtained
7. Preventable, drug known to cause toxicity - continuous monitoring required, not performed
8. Preventable, drug ordered inappropriate for patient Dx

ADVERSE DRUG REPORT

Date: _____

Date Occurred	Medical Record #	Drug Involved	Severity Level	Prevent Level	Reported Patient Reaction/Symptoms	Treatment Ordered	Patient Outcome

Severity (S) Levels:

1. No action necessary, reaction minor
2. Change Rx, no treatment necessary
3. Change Rx, treatment instituted
4. Change Rx, provide Tx, requires admission or longer LOS
5. Change Rx, provide Tx, requires transfer to higher acuity unit (ICU/CCU)
6. Change Rx, provide Tx, results in irreversible harm/injury
7. Results in death

Preventability (P) Levels:

1. Unpreventable, Rx appropriate for Dx
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3. Possibly preventable, drug-drug interaction noted
4. Possibly preventable, food-drug interaction noted
5. Preventable, documented patient allergy
6. Preventable, drug known to cause toxicity - no levels obtained
7. Preventable, drug known to cause toxicity - continuous monitoring required, not performed
8. Preventable, drug ordered inappropriate for patient Dx

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PURPOSE/OBJECTIVE:

- The Pharmacy Department participates in a performance improvement (PI) program designed to monitor, evaluate and improve the quality, appropriateness and outcomes of clinical services by:
    - Planning, designing, measuring, assessing, improving new or revised processes of patient care and service,
    - Identifying opportunities through continuous assessment of systems and processes of care through a collaborative, interdisciplinary focus,
    - Implementing solutions and actions which will bring about the desired changed, to
    - Facilitate a positive patient outcome, while
    - Maintaining a safe environment of personnel; patients and visitors.

RESPONSIBILITY:

- The Pharmacy Director is responsible for establishing and implementing a performance improvement plan for sterile compounding procedures as well as a performance improvement plan for the entire department. The plan shall integrate Pharmacy Department quality assessment/improvement, continuous quality improvement (CQI) and quality control activities into a system that will foster improvement in patient care. The Pharmacy Director also shall delegate responsibilities for monitoring, action, evaluation and reporting.

- The Pharmacy Director will report all Pharmacy Department performance improvement activities to the Pharmacy and Therapeutics Committee for their review and recommendations.

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GOALS OF PERFORMANCE IMPROVEMENT:

- The primary goals of the Pharmacy Department performance improvement plan are to continually and systematically plan, design, measure, assess and improvement performance of priority focus areas, improve healthcare outcomes and reduce and prevent medical/health care errors. To achieve these goals the plan strives to:
  - Incorporate quality planning;
  - Provide for a program that assures the department designs processes (with special emphasis on design of new or revisions in established services) well and systematically measures, assesses and improves its performance to achieve optimal patient health outcomes in a collaborative, cross-departmental, interdisciplinary approach. These processes include mechanisms to assess the needs and expectations of the patients and their families, staff and others. Process design contains the following focus elements:
    - Consistency with the organization's mission, vision, values, goals and objectives, and plans
    - Meets the needs of individuals served, staff and others
    - Use of clinically sound and current data sources (for instance, information from relevant literature and clinical standards)
    - Is based upon sound business practices
    - Incorporates available information from internal sources and other organizations about the occurrence of medical errors and sentinel events to reduce the risk of similar events in this institution
    - Utilizes the results of performance improvement, patient safety and risk reduction activities
- The Pharmacy Department incorporates information related to these elements, when available and relevant, in the design or redesign of processes, functions or services.
- The status of identified problems is tracked to assure improvement or problem resolution.

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- Information and the findings of discrete performance improvement activities and adverse patient events are used to detect trends, patterns of performance or potential problems that affect more than one (1) department/service.

- The objectives, scope, organization and mechanisms for overseeing the effectiveness of monitoring, assessing, evaluation and problem-solving activities in the performance improvement program are evaluated annually and revised as necessary.

- Treatment and services affecting the health and safety of patients are identified. Included are those that occur frequently or affect large numbers of patients at risk of serious consequences or deprivation of substantial benefit if care is not provided correctly or not provided when indicated; or care provided is not indicated, or those tending to produce problems for patients, their families or staff.

SCOPE OF CARE:

- Patient services are provided to both the inpatient and outpatient population across the life span. Pharmacy services are provided 24 hours a day, seven (7) days a week and include:
  - Selection and procurement of medications
  - Storage of medications
  - Preparation of medications
  - Medication dispensing
  - Drug utilization monitoring
  - Drug information to the hospital staff
  - Patient/family/staff counseling and education
  - Inservice to nursing and hospital staff
  - Compounding services

PERFORMANCE ACTIVITIES:

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- The performance improvement program for the Pharmacy Department shall monitor priority focus areas and processes of care which are felt to be high-risk, high volume, have demonstrated a trend toward potential negative patient outcome (problem prone) and/or that involve risks that may result in sentinel events or have been identified through the continuous quality improvement (CQI) process as an area where a system or process of patient care may be improved.

- Additional indicators will be identified and chosen for monitoring through a collaborative effort utilizing information obtained from all areas of Nursing Services, administration, medical staff evaluation, regulatory body reports, patient care questionnaires and other clinical services throughout the facility, as appropriate.

- Proposed processes for assessment include, but are not limited to:

    - Medication errors - wrong drug, dosage, time, route or rate of administration; wrong patient; omission, duplication or administration without an order
    - Adverse reaction to medication
    - Medication order filled incorrectly
    - Occurrences that have an adverse result on a patient
    - Equipment breakage/failure that has an adverse result on a patient
    - Equipment not available
    - Security incident
    - Expired, recalled or otherwise unusable drug dispensed
    - Incorrect or incomplete labeling of CSPs
    - Patient/family education

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- Drug recall measures
- Research investigational drugs
- Surveillance, prevention and control of infection
- Patient/visitor/personnel safety management
- Instrument preventive maintenance and safety assessments
- Patient confidentiality
- Sentinel event reduction and elimination
- Ambulatory Pharmacy services
- Patient satisfaction
- Technical quality control activities

- Performance monitoring of identified processes are subject to change due to the collaborative process outlined above.

PERFORMANCE MEASURES:

- Performance measures with related performance outcomes will be established as a means to systematically monitor the identified processes for review in an ongoing manner, and to provide operational linkages between the risk management functions related to the clinical aspects of patient care and safety and the performance improvement functions.

- Performance expectations will be established for any new or revised processes undertaken by the Pharmacy Department staff. Performance measures will be specific and measurable. Performance measures will be structured and related to both the processes and outcomes of patient care.

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- Performance measures will pertain directly to Pharmacy Department compounding practices and will use objective criteria that reflects current knowledge and clinical practice.
  - The following criteria will be utilized to assure that the indicator chosen for data collection is the most appropriate for monitoring the performance of a patient care of service process, system or function:
    - The measure can identify the events it was intended to identify.
    - The measure has a documented numerator and a denominator statement or description of the population to which the measure is applicable.
    - The measure has defined data elements and allowable values.
    - The measure can detect changes in performance over time.
    - The measure allows for comparison over time within the organization or between the organization and other entities.
    - The data intended for collection is available and attainable.
    - Results can be aggregated and reported in a way that is useful to the organization and other interested parties.
  - Examples of Pharmacy Department Performance Measures (specific to CSPs):
    - CSPs verified by Pharmacy personnel other than the compounder
    - # of dispensing errors
    - # of computer order entry errors
    - # of labeling errors
    - # of adverse drug events
    - Equipment malfunction

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- Air quality not up to standard
- # of times refrigerator/freezer is out of range for correct temperature
- Aseptic technique not followed
- Clean room attire procedures not followed
- Hand scrub procedures not followed
- Validation results
- Failed compounding competence assessment (staff competency)
- Sterilization parameters not followed
- Cleaning and disinfection of work environment not completed per policy and procedure
- # of errors found when performing compounding accuracy checks

THRESHOLDS:

Measurement of performance measures will be structured to focus on an improvement in patient care. Thresholds will represent either preestablished levels, that when reached trigger an intensive evaluation of the measure under review, or benchmarks that have been identified by facility experience, that require an indepth evaluation of the proposed performance aspect and related performance measures. Threshold will also serve as a means to identify targeted areas for further study.

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METHODOLOGY:

- The Pharmacy Department utilizes the Plan, Do, Check, Act (PDCA) methodology to plan, design, measure, assess and improve functions and processes related to major patient care related activities.
  - **Plan:**
    - Performance measures are based on current knowledge and experience and are structured to represent cross-departmental, interdisciplinary processes, as appropriate.
    - The following data sources will be reviewed for use in the development of performance measures:
      - Staff opinions and needs
      - Staff perceptions of risks to patients and suggestions for improving patient safety
      - Staff willingness to report medical/health care errors
      - Outcomes of processes or services, including adverse events
      - Autopsy results if available
      - Performance measures from organization approved internal and external databases
      - Infection control surveillance and reporting
      - Satisfaction surveys
      - Risk management

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- Medication management review process
- Quality control
- Customer demographics and diagnoses

- Benchmarks or thresholds that trigger intensive assessment and evaluation are established.

- **Do:**
  - Data is collected to determine:
    - Whether the design specifications for new processes were met
    - The level of performance and stability of existing processes
    - Priorities for possible improvement of existing processes

- **Check:**
  - The Pharmacy Director and the department as a whole shall review and evaluate the data presented for analysis of outcomes. Appropriate statistical methodology will be employed to analyze and display data. Evaluation shall focus on identifying opportunities to improve both the processes of patient care and actual identified problem areas that effectuate a negative outcome, as well as the reduction and/or elimination of real or potential sentinel events. Comparisons with both internal, department specific historical data and external data will be performed in the evaluation process, with undesirable patterns or trends in performance and sentinel events requiring intensive analysis. Conclusions will be drawn regarding the evaluation of data presented with recommendations considered.

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- **Act:**
  - Upon review of the data presentation, conclusions and recommendations, the Pharmacy will take actions to resolve identified problems and will direct efforts to those areas which have the greatest potential for improving patient care and reducing the risk of sentinel events. The Pharmacy Department shall utilize existing resources, committees and problem-solving techniques to resolve identified problems and improve patient care and safety. The Pharmacy will perform follow-up monitoring to assure that actions taken are effective and than any progress achieved is sustained. The criteria used for follow-up monitoring should be the same or similar to those used in the initial identification of the problem/opportunity for improvement, however, the sample size may vary or focused monitoring may be utilized for effectiveness.

COMMUNICATION/INTEGRATION OF INFORMATION:

- The Pharmacy Director shall ensure that documentation of the results of the outcomes of performance improvement and patient safety activities are maintained and that reports are forwarded as prescribed by the organizationwide performance improvement plan. Pharmacy staff committees reviewing the outcome of the Pharmacy's ongoing performance improvement activities include: Pharmacy and Therapeutics Committee. The frequency of reporting will be as defined in the organizationwide performance improvement plan, on a monthly/bimonthly/quarterly basis as designated. Documentation and reports shall include:
  - Findings from monitoring activities
  - Conclusions regarding identified opportunities for improvement
  - Recommendations concerning potential actions
  - Actions take to effectuate change
  - Outcome of action effectiveness (results of follow-up monitoring performed to determine extent of effectiveness and that improvements made are sustained)

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ANNUAL EVALUATION OF PERFORMANCE IMPROVEMENT PROGRAM:

The Pharmacy shall evaluate the effectiveness of the performance improvement monitoring and evaluation program at least annually and revise as necessary. Other sources that interact with the Pharmacy during the course of patient care activities will be encouraged to participate in the evaluation of effectiveness of the program. The evaluation shall be documented and forwarded through the appropriate medical staff reporting structure to the Governing Body.

CONFIDENTIALITY:

- All information related to performance improvement activities performed by the pharmacy staff and personnel in accordance with the plan are confidential.
    - Confidential information may include but is not limited to: the medical staff committee minutes, Performance Improvement Executive Report, electronic data gathering and reporting, untoward incident reporting and clinical profiling..
    - Some information may be disseminated on a "need to know basis" as required by agencies such as federal review agencies, regulatory bodies, the National Practitioners Data Bank or any individual or agency that proved a "need to know basis" as approved by the Governing Body.

PHARMACY DEPARTMENT PI PLAN APPROVAL:

Pharmacy Director	Date
Pharmacy and Therapeutics Committee Chairperson	Date
Performance Improvement Committee Chairperson	Date

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POLICY:

- The Pharmacy and Therapeutics Committee shall implement a Medication Management Assessment and Evaluation Program to provide a system to ensure medication use within the organization is conducted in a safe and optimal manner.

- The Medication Management Assessment and Evaluation program requires the routine evaluation of literature for new technologies and best practices that have been demonstrated to enhance safety in other organizations to determine if these practices are conducted successfully within the organization or if they should be implemented to improve the medication management system.

- The Medication Management Assessment and Evaluation Program identifies risk points (including medication errors and adverse drug reactions) and identifies areas to improve patient safety as well as the overall use of medications throughout the organization.

- For the purposes of this program the definition of medication includes:
  - Prescription medications
  - Sample medications
  - Herbal remedies
  - Vitamins
  - Nutraceuticals (substances not controlled by the FDA, not proven beneficial by authoritative sources, however the public commonly utilizes, i.e., Ingestible Shark Cartilage)
  - Over-the-counter drugs
  - Vaccines
  - Diagnostic and contrast agents
  - Respiratory therapy treatments
  - Parenteral nutrition
  - Blood derivatives

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- Intravenous solutions (plain, with electrolytes and/or other drugs)
- Any product designated by the FDA as a drug

- The Pharmacy and Therapeutics Committee will maintain oversight for the Medication Management Assessment and Evaluation Program. The program is based on the principles of performance improvement, with a focus on identification and measurement of processes and activities that are high-volume, high-risk, problem-prone and patient safety related. The program includes data collection and measurement of medication management processes, identification of opportunities or areas of improvements, the testing of incremental improvements and the recommendation of improvements to the organization's leaders. The main goal of improving the performance of medication management processes is to continuously improve patient health outcomes and reduce the occurrence of medication related errors and medication related adverse patient outcomes, including adverse drug reactions. The following essential processes will be conducted to adequately assess and evaluate how medication is managed throughout the institution.
  - Process Design
  - Performance Measurement
  - Performance Assessment
  - Performance Improvement
- The Pharmacy Director is responsible for reporting medication management processes to the Pharmacy and Therapeutics Committee, whose members in turn are responsible for assessing, monitoring and evaluating the processes and outcomes of the medication management throughout the institution.

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PROCEDURE:

- The Pharmacy and Therapeutics Committee will collaborate and work together as a team with the Pharmacy Director, and other designated members of the institution, to develop, implement and evaluate the organizationwide Medication Management Assessment and Evaluation Program. As appropriate to the setting, individuals involved in the system of medication management include licensed independent practitioners, healthcare professionals and staff involved in medication management processes.
    - Assessment and Evaluation Process: The following core medication management processes carried out by the organization are measured, assessed and evaluated:
        - Selection and procurement
        - Storage
        - Ordering and transcribing
        - Preparing and dispensing
        - Administration
        - Monitoring the effects and side effects on patients
    - Over time, data is collected on all of the above processes.
- The Pharmacy Department provides fundamental functions as well as key oversight responsibilities and activities in the system of medication management. The Pharmacy Department performs the following functions and activities:
    - Selection and procurement of medications
    - Storage of medications
    - Maintenance of adequate medication inventory
    - Oversight of ordering and transcribing processes

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- Preparation of medications
- Medication dispensing
- Direct and indirect scheduled medication security and control
- Drug floor stock distribution
- Drug utilization monitoring and evaluation
- Provision of drug information to the organization's staff
- Patient/family/staff counseling and education
- Provision of formal and informal inservice to the nursing and other staff licensed to administer medications
- Provision of IV additive service
- Clinical dosing of specific medications (i.e., aminoglycosides)

- The Pharmacy Department will be responsible to monitor the outcomes of its important functions and activities through internal performance improvement activities through investigation, data collection and monitoring of the internal processes conducted within, or by, the Pharmacy and its personnel. External performance improvement activities related to medication management will be monitored by the Pharmacy Department through data collection from a wide variety of sources including, but not limited to, medication error reports (which include real and potential errors), and adverse drug reaction reports.

- The Pharmacy Department will collect data systematically for improvement priorities and continuing measurement. The process of data collection activities will be (when appropriate and as often as possible) collaborative and interdisciplinary in nature.

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- To adequately monitor and evaluate the medication management system in place within the institution the Pharmacy Department collects data on the following:
  - Processes and outcomes
  - Medication errors (real and potential)
  - Adverse drug reactions
  - High-risk, high-volume and problem-prone processes
  - Patients needs, expectations and department specific patient satisfaction questionnaires and/or surveys
  - Infection control activities
  - Patient safety reports
  - Current literature for new technologies and best practices
  - Risk management issues and findings
  - Sentinel events

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- Performance Measures:
  - Administration of medication is of high-risk and therapeutic benefit to the patient. Medication management processes are measured on an ongoing basis. The following are performance measures or categories of measures for which data is collected, aggregated, reviewed and analyzed in an effort to identify risk points and areas to improve patient safety. The list is not exhaustive and may be revised in accordance with data collected, which may indicate the benefit of inclusion or exclusion of a performance measure from the monitoring and evaluation cycle. Measures include, but may not be limited to:
    - Medication errors - wrong drug, dosage, time, route or rate of administration, wrong patient, omission, duplication or administration without an order, adverse reaction to medication (includes potential errors or "near misses")
    - Medication order filled incorrectly
    - Medication order prepared incorrectly
    - STAT medication not sent within established time frames
    - Controlled substance missing and/or incorrect count
    - Occurrences that have an adverse result on a patient
    - Equipment breakage/failure that has an adverse result on a patient
    - Equipment not available
    - Security incident
    - Expired, recalled or otherwise unusable drug dispensed
    - Formulary management
    - Labeling of drugs

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- Education of patients and family
- Drug recall measures
- Surveillance, prevention and control of infection
- Research investigational drugs
- Ambulatory Pharmacy Services
- Management of Human Resources (i.e., licensure requirements and entry level qualifications)
- Patient outcomes; long and short range continuing education
- Technical quality control activities
- Adverse drug reactions

- Drug Usage Evaluation is an important component of the Medication Management Assessment and Evaluation Program. The Pharmacy and Therapeutics Committee, acting on behalf of the medical staff shall implement as a component of the overall Medication Management Assessment and Monitoring Program a Drug Usage Evaluation Program to ensure the safe, appropriate and efficacious use of medications throughout the institution. Drug usage will be monitored in a systematic and continuous manner. The Pharmacy and Therapeutics Committee will determine the specific medications to be evaluated as well as the criteria to be applied. Based on the findings of the Drug Usage Evaluation Program, the Pharmacy and Therapeutics Committee will forward recommendations to the medical staff to correct or improve medication use.

- The Drug Usage Evaluation Program will present to the Pharmacy and Therapeutics Committee an annual plan (i.e., schedule) by which medications will be assessed in the forthcoming year.

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- Priorities for the selection of medications for evaluation shall be based on one (1) or more of the following factors:
    - The number of patients affected by the medication use (i.e., frequency of medication use)
    - The significance, including degree of risk, to individual patients
    - The degree to which use of the medication is known or suspected to be problem-prone
    - Ability to improve the outcome of a specific disease for which medication is an integral part of the treatment
- Criteria for evaluation will be developed by the Pharmacy Department, based on objective measures that reflect the appropriate use of the medication as determined by community medical standards, current literature and best practices. The evaluation shall focus on processes that measure:
    - Prescribing or ordering of medications
    - Transcribing of medications
    - Preparing and dispensing
    - Administration
    - Monitoring the medications' effects on patients
- Criteria for evaluation shall be approved by the Pharmacy and Therapeutics Committee prior to an evaluation being performed.
- The Pharmacy Department, in conjunction with the medical staff, will conduct the evaluations, obtaining quantitative data and present a written report of findings to the Pharmacy and Therapeutics Committee on a quarterly basis. Reports shall include criteria, findings, causes/conclusions and recommendations.

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- The Pharmacy and Therapeutics Committee will determine actions to be recommended to the medical staff based on an analysis of:
  - Thresholds or control limits exceeded
  - Undesired patterns or trends
  - Opportunities to improve performance or minimize adverse reactions
- To adequately address the amount of medications that may prove beneficial for drug usage evaluation priorities for ongoing assessment have been developed. These priorities are based upon the following:
  - The number of patients taking a medication
  - The balancing of risk with therapeutic potential
  - Medications known or suspected to be problem-prone
  - Therapeutic effectiveness, (i.e., use of antibiotics to treat pneumonia)
- The Pharmacy and Therapeutics Committee shall determine if, and when, a medication evaluation requires discontinuation or needs to be continued as a:
  - Full evaluation
  - Limited evaluation

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APPROVED BY: SHABANA YASMIN	REVISED:

- Based on the findings of the Drug Usage Evaluation Program, the Pharmacy and Therapeutics Committee will forward recommendations to the medical staff to correct or improve medication use.
    - The performance assessment process conducted for evaluation of the medication management program, as a whole is systematic, interdisciplinary and interdepartmental. The Pharmacy Department uses a systematic process to assess collected data. Other disciplines will collect data related to medication management processes conducted within their department. The assessment process will include statistical quality control techniques as needed. Data assessment begins with a clear understanding of the medication management processes under review. The framework for systematic assessment includes the multidisciplinary analysis of data to answer questions about the processes and outcomes that are being monitored throughout the organization. The following issues shall be assessed and evaluated:
        - Current level of performance
        - Stability of current processes
        - Identification of areas that could be improved
        - Identification of improvement priorities
        - Effectiveness of strategies implemented to improve performance
        - Specifications for new or redesigned processes determined and met
- An interdisciplinary approach will be made to make comparisons of processes and outcomes over time. The data will be compared and reference databases utilized as needed. Priorities for improvement will be assessed. Improvement activities will be implemented based upon assessment conclusions. The Pharmacy Department as well as the Pharmacy and Therapeutics Committee (as appropriate) will collaborate as necessary with other disciplines throughout the organization.

SUBJECT: MEDICATION MANAGEMENT PROGRAM	REFERENCE #1062
	PAGE: 11
DEPARTMENT: MED-PLUS PHARMACY IV	OF: 12
	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

- The organization will systematically improve the performance of its medication management system. The Pharmacy and Therapeutic Committee will assess and evaluate data provided and will determine and implement strategies to improve performance. The Pharmacy and Therapeutics Committee will implement actions that result in desired, measurable changes in processes. To achieve improvements and improve patient safety, the Pharmacy and Therapeutics Committee will participate in the following performance improvement activities:
  - Planning
  - Testing
  - Assessing results and redesigning if necessary
  - Implementing
  - Assessing the effectiveness of implemented actions
  - Reevaluation as deemed necessary to assure gains made are sustained
- Performance improvements will be based on:
  - Evaluation of the hospital's medication management system
  - Review of new technologies
  - External data
  - Medication practices that have been proven successful and have enhanced patient safety
- Practitioner specific outcomes of medication management assessment and evaluation review will be included in the practitioner's quality and competency profile for reappointment purposes. This includes review outcome of Drug Usage Evaluation and other clinically significant issues within the Medication Management Assessment and Evaluation Program as a whole.

SUBJECT: MEDICATION MANAGEMENT PROGRAM	REFERENCE #1062
	PAGE: 12 OF: 12
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: SHABANA YASMIN	REVISED:

ANNUAL REVIEW:

- The Medication Management Assessment and Evaluation Program will be assessed and measured annually for its effectiveness and consistency within the improving organization performance framework in place within the facility. If the identified improvements are not realized within a defined time period, the organization will reexamine the process within the function that is being monitored. The findings, conclusions, recommendations and actions will be communicated by the Pharmacy and Therapeutics Committee to the following:
  - Leadership Team
  - Patient Safety Committee
  - Organization Performance Improvement Committee
  - Governing Body

SUBJECT: Guidance for Extended Use and Limited Reuse of PPE	REFERENCE #1065
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 03-11-2020
APPROVED BY: FLYNN LEW	REVISED:

POLICY:

This policy outlines the practice for extended use and limited reuse of PPE. Supplies of PPE devices can become depleted during influenza pandemic or wide-spread outbreaks of other infectious respiratory illnesses. This strategic policy conserves protective garb while maintaining the highest level of containment and limiting exposure of compounded sterile products to contaminants.

PROCEDURE:

A. Inventory the pharmacy's current supplies of PPE (personal protective equipment) to estimate how long the specific PPE supply will last under current policies.
   1. If current supply is running low, attempt to order more without hoarding.
   2. If current supply and future ordering capability cannot sufficiently provide two months' worth of supplies, consider immediate implementation of this policy.

B. Prior to initializing any guidance in this policy, the Pharmacist-In-Charge is to acquire a waiver from the California Board of Pharmacy.
   1. The granted waiver, to deviate from the single-use provision in USP <797>, shall be retained and stored for future reference.
   2. A individual waiver is not required if the board of pharmacy proclaims pharmacy law waivers in response to state or national declaration of emergencies.

C. Utilize existing SOP to limit exposure and limit use of PPE.
   1. Limit personnel entering the clean room
      i. Exclude anyone exhibiting signs of any illness
      ii. Reduce the number of personnel engaged in compounding activities
      iii. Stage supplies outside the compounding area
      iv. Minimize trips into the clean room
   2. Limit contamination
      i. Ensure personnel hygiene
      ii. Wear freshly laundered scrubs every day
      iii. Meticulous disinfection
      iv. Walk slowly and deliberately in the clean room
      v. Re-sanitize frequently
      vi. Avoid talking while compounding
      vii. Do not touch face mask after donning.

SUBJECT: Guidance for Extended Use and Limited Reuse of PPE	REFERENCE #1065
DEPARTMENT: MED-PLUS PHARMACY IV	PAGE: 2 OF: 3
	EFFECTIVE: 03-11-2020
APPROVED BY: FLYNN LEW	REVISED:

B. Response to shoe cover shortage
   1. Consider use of cleanable, facility-dedicated shoes that are not worn outside the compounding area.
   2. Source alternative shoe covers, such as those used on construction sites
   3. Do not reuse shoe covers, including turning them inside out for reuse.
   4. Develop systems to deliver materials to compounding employees to reduce garb change required when entering the compounding space.
   5. The use of pass-throughs and dedicated carts should be formalized and maximized.

C. Response to face mask shortage
   1. If available, substitute N-95 masks for clean room masks. When using N-95 mask for non-HD sterile compounding procedures, fit testing is not required.
   2. Limited reuse of face masks used in non-HD compounding.
      i. Store the used face mask in a new, paper bag (or something clean and breathable) after each use.
      ii. Face mask should never be shared between employees
      iii. Retained masks should be stored where they are donned, individually identified, donned prior to hand washing, and not touched after proper placement.
      iv. Retained masks should be replaced when the mask condition is questionable, the mask is visibly soiled, or after 72 hours of use.

D. Response to gown shortage
   1. Decrease the number of employees in the sterile compounding area to reduce use.
   2. Retain and reuse gowns for an entire shift/day.
   3. If gowns are reused for longer periods of reuse (no more than 1 week), store them on individual hooks. Do not store them inside out.
      i. Gowns should be stored on the clean side of the ante room away from the sink.
      ii. Gowns should be stored when they are visibly soiled or after one (1) week of use.
      iii. Gowns used for cleaning or HD compounding should not be retained or reused.

E. Response to hand sanitizer shortage
   1. Consider limiting hand sanitizer use to glove change procedures only.
   2. Alcohol-based hand sanitizer not intended for clean room or surgical use may be utilized as a replacement.

SUBJECT: Guidance for Extended Use and Limited Reuse of PPE	REFERENCE #1065
	PAGE: 3 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 03-11-2020
APPROVED BY: FLYNN LEW	REVISED:

F. Environmental Monitoring
   1. Implementation of Policy 1065 requires additional environmental monitoring in the PEC use for sterile compounding.
   2. Weekly, dynamic microbial surface sampling inside the PEC on the Direct Compounding Area (DCA)
      i. If growth occurs, consider changes to supply cleaning/disinfecting procedures, changes to the procedure for material transfer into the PEC, or increasing the frequency of DCA sanitation procedures. Further testing growth to genus level when growth exceeds action levels.
      ii. If a growth occurs that exceeds action levels, retrain staff, resample the site, and potentially decrease the BUD until a compliant sample is obtained.
   3. If weekly dynamic microbial surface sampling inside the PEC is not possible, BUDs will be limited to 12 hours at room temperature or 24 hours under refrigeration.

G. HD Compounding and PPE garb shortage
   1. Garb used in HD compounding should not be reused.
   2. Implementation process workflow to reduce use of critical PPE shortage:
      i. Grouping HD compounding together.
      ii. Designating a time when HD compounding is performed.
      iii. Adjusting personnel schedules to limit the number of HD compounding personnel.
      iv. Handling HD outside a PEC (per Assessment of Risk, AoRs)

REFERENCE:

Iowa Board of Pharmacy: What should my pharmacy do if we have limited supplies of compounding garb?

CDC Pandemic Planning: Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings.

SUBJECT: POLICY AND PROCEDURE FOR NOTIFYING STAFF OF COMPOUNDING POLICY AND PROCEDURE CHANGES AND REVIEW BY PHARMACIST-IN- CHARGE	REFERENCE #1100
	PAGE: 1 OF: 1
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 12/04/20

POLICY:

- It is the policy of this pharmacy to notify staff assigned to compounding duties of any changes in process or to the compounding policy and procedure manual. In addition, it is our policy that the compounding policy and procedure manual will be reviewed by the pharmacist-in-charge on an annual basis, and updated whenever changes in process are implemented.

PROCEDURE

- Whenever there is a change in a policy or procedure with respect to compounding, all staff assigned to compounding duties will be notified of the change, and proof of this notification will be documented and filed in the pharmacy in a readily retrievable form for at least three years.
    - Notification methodology may include, but not restricted to the following:
        - Printed format
        - Email
        - Stand-up meetings

- On or before July 1st of every year, the pharmacist in charge will review the policy and procedures with respect to compounding, and proof of review will be documented and filed in the pharmacy in a readily retrievable form for at least three years.

- The pharmacist-in-charge will update the compounding policy and procedures whenever changes in processes are implemented.

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 1 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

DEFINITIONS

- The FDA has classified recalls according to the following guidelines:
- **Class I**: A situation in which there is reasonable probability that the use of, or exposure to, a volatile product will cause serious adverse health consequences or death.
- **Class II**: A situation in which the use of, or exposure to, a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III**: A situation in which the use of, or exposure to, a volatile product is not likely to cause adverse health consequences.

POLICY

- All recalled products would be removed from the compounding storage area, storage shelves and will-call area if a compounded prescription was compounded with the recalled product. The recalled product(s) will be quarantined until returned to the manufacturer or destroyed as per manufacturer instructions. In the event it is discovered that a compounded product does not pass our quality control, it is our policy to remove the product from out compounding area. In the event quality verification demonstrates the potential for adverse effects with continued use of the compounded drug product, patients who have received the compounded product would be notified and if possible, the compounded product would be recovered, in addition the prescriber and the state board of pharmacy will be notified.

PROCEDURES

- Identification of Product Recall Information: At our Pharmacy, product recall information is identified through several methods, including notification from the wholesaler, manufacturer, California State Board of Pharmacy and/or the FDA. Notification will typically be in written form via fax, e-mail, or mail.. This notification will be directed to or immediately forwarded to the Pharmacist-in- charge and/or compounding technician.

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 2 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

- Product Recall Assessment/Inventory Detection: Following receipt of recall information, the receiving party will determine if the product is stocked within the areas listed above.
- Recall Action/Information Dissemination
- Target Product Not Stocked: If the recalled product is not stocked, the following information is documented directly on the recall notice: identification of the product not being stocked, date, action, and initials of the reviewer. Records will be maintained in a binder.
- Target Product Stocked: Class II and III Recall:
- Identification: The pharmacist-in-charge and/or compounding technician will identify the location of the recalled medications
- Disposal/Return: Once the targeted item is identified the appropriate actions are taken in accordance with the manufacturer's recommendations and guidelines. The pharmacist-in-charge and/or compounding technician will supervise and ensure the removal of recalled product from stock immediately, quarantine and disposal/return via recall guidelines.
- Documentation: Retrieval and disposal/return of recalled product will be documented on the recall form sent from the manufacture/wholesaler by the pharmacist- in-charge and will include: date, recall classification, return date, quantity of stock, disposition, and initials. Records will be maintained in a binder
- Target Product stocked : Class I Recall - Because Class I recalls can have serious health consequences; the following additional measures will be taken in such cases
- Identification: The pharmacist-in-charge and/or compounding technician will identify the location of the recalled medications.
- Disposal/Return: Once the targeted item is identified the appropriate actions are taken in accordance with the manufacturer's recommendations and guidelines. The pharmacist-in-charge and/or compounding technician will supervise and ensure the removal of recalled product from stock immediately, quarantine, and disposal/return via recall guidelines
- Documentation: Retrieval and disposal/return of recalled product will be documented on the recall form sent from the manufacture/wholesaler by the pharmacist-in-charge and will include: date, recall classification, return date, quantity of stock, disposition, and initials. Records will be maintained in a binder.

SUBJECT: POLICY AND PROCEDURE FOR DRUG RECALL	REFERENCE #1102
	PAGE: 3 OF: 3
DEPARTMENT: MED-PLUS PHARMACY IV	EFFECTIVE: 05/04/09
APPROVED BY: FLYNN LEW	REVISED: 06/20/2023

- Identification of Patients Receiving Recall Medication: The pharmacy will identify, via the pharmacy computer system, a list of patients who potentially received the targeted product. The pharmacy will then attempt to contact each patient by phone and/or by mail if the patient cannot be reached by phone.

- Notification

    - Issuance of a recall notice of a sterile compounded drug notice shall be done as soon as possible and notifications of the following entities, within 12 hours of the recall notice release:

        - Prescriber
        - Patient
        - State Board of Pharmacy

    - The 12-hour notification is mandated if: use of or exposure to the recalled drug may cause serious adverse health consequences or death within the state of California.

ATTACHMENT A

MED-PLUS PHARMACY LTC

ASSESSING HAND HYGIENE AND GARBING RELATED PRACTICES OF COMPOUNDING

Printed Name and Position/Title of Person Assessed: _____

Name of Facility or Location:

Hand Hygiene and Garbing Practices:

The qualified evaluator will mark (X) each space for which the person being assessed has acceptable completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

_____ Presents in a clean appropriate attire and manner.
_____ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities
_____ Dons shoe covers or designated clean-are shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
_____ Dons beard cover if necessary.
_____ Dons head cover assuring that all hair is covered.
_____ Dons face mask to cover bridge of nose down to include chin.
_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
_____ Dries hands and forearms using lint-free towel or hand dryer.
_____ Selects appropriate size gown examining for any holes, tears or other defects.
_____ Disinfects hands again using waterless alcohol-based surgical hand scrub with persistent activity and allows hand to dry thoroughly before donning sterile gloves.
_____ Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
_____ While engaging in sterile compounding activities, routinely disinfects gloves with 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
_____ Removes PPE on the clean side of the ante-area.
_____ Removes gloves and performs hand hygiene.
_____ Removes gown and discards it, or hangs it on the hook if it is to be reused within the same working day.
_____ Removes and discards mask, head cover, and beard cover (if used).
_____ Removes shoe covers or shoe one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. Removes and discards shoe covers every time the compounding area is exited).

* The person assessed is immediately informed of all unacceptable activities (e.g., spaces lacking a check mark, N/A or N/O are shown and informed of specific corrections.

Signature of Person Assessed | Printed Name | Date

Signature of Qualified Evaluator | Printed Name | Date

ATTACHMENT B

MP

PRINTED NAME AND POSITION/TITLE OF PERSON ASSESSED: _____

Assessing Cleaning and Disinfection Procedures

Cleaning and Disinfection Practices: The qualified evaluator will mark (x) each space for which the person being assessed has acceptable completed the described activity, prints N/A if the activity is not applicable to the assessment session of N/O is the activity was not observed

Daily Tasks:

___ Prepares correct concentration of disinfectant solution according to manufacturer's instructions.

___ Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).

___ Documents disinfectant solution preparation.

___ Follows garbing procedures when performing any cleaning activities.

___ At the beginning of each shift, cleans all ISO class 5 device prior to compounding in the following order: ceilings, walls, IV bar, and work surface.

___ Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.

___ Removes all compounder components and cleans all ISO class areas as stated above at the end of each shift.

___ Cleans all counters and easily cleanable work surfaces.

___ Mops floors, using mop labeled "floors", starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator; moves carts as needed to clean entire floor surface. Use of microfiber cleaning system is an acceptable alternative to mops.

___ In the ante-area cleans sink and all contact surfaces; cleans floor with disinfectant solution or uses microfiber cleaning system.

Weekly Tasks:

___ Performs weekly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaced to be cleaned.

___ Cleanse buffer area and ante-area ceiling, walls, and storage shelving with disinfectant solution and a mop or uses a microfiber cleaning system.

___ Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.

___ Cleans all buffer area totes and storage shelves by removing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.

___ Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the underside of the shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes cart with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.

___ Cleanse buffer area chairs; the interior and exterior of trash bins and storage bins using disinfectant solution soaked lint free wipe.

___ Documents all cleaning activities as to who performed such activities with date and time noted.

***The person assessed is immediately informed of all unacceptable activities (i.e. spaces lacking a Check mark, N/A or N/O and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

MP®

GroMed™ Media LOG

Employee Name:

							RESULTS											
							20-25°C						30-35°C					
							Incubate first 7 Days						Incubate second 7 Days					
Date	Time	Technician Prep Initial	Hood #	Media Lot #	Media Expiration	Process Tested	Date	Time	Temp	Negative	Positive*	Initial Read by	Date	Time	Temp	Negative	Positive*	Initial Read by

* Positive is indicated by visible turbidity or other visual manifestations of growth in the media on or before 14 days.

PATT 2™

Personal Aseptic Technique Test

Catalog #GM7030

For Low and Medium Risk Levels

Q.I.medical, inc

Nevada City, CA 95959
(530) 265-4820 • FAX (530) 265-9416
www.qimedical.com • info@qimedical.com

Note: Validation of high risk manipulations may require additional supplies and equipment. If necessary, modify the suggested steps to more closely simulate the most challenging aseptic manipulations performed at your pharmacy. Non-sterile TSB media can be prepared by starting with #GM3000, Soybean-Casein Digest. It is packaged in convenient 3 gram pouches.

1. This procedure is one of the more complex of those the operator will be expected to perform. It consists of adding the contents of an ampule to a vial, then transferring 20 portions of a vial to a partially filled minibag.

2. Sanitize work area using standard procedures. Swab vial and bag ports according to the pharmacy's standard operating procedures.

3. Select 1 GroMed ampule, 1 GroMed partially filled minibag, and 1 GroMed 20 ml vial, each containing sterile Trypticase Soy Broth growth medium. Wipe the ampule and injection ports of the bag and vial with a wipe dampened with IPA. If using a laminar airflow hood place the containers at least 6 inches within the work area so as to protect the injection ports and not interrupt the clean air flow.

4. Select 20 sterile 18G x 1" needles (or smaller size as appropriate) and one sterile 3, 5, or 6cc disposable syringe. Remove the syringe from the pouch and place the syringe in the work space.

5. Aseptically attach a needle to the syringe.

6. Draw up contents of the ampule and inject into the GroMed vial. Shake to mix indicator dye.

7. Withdraw 1 ml of TSB from the GroMed vial and inject the TSB into the bag of sterile TSB. Change the needle. The frequent needle changes make the complexity of the procedure approach a "worst case" situation.

8. Repeat procedure (#7) 19 more times, using 19 different needles but the same syringe and receiving bag of TSB. The final transfer should empty the contents of the vial. At the end of these transfers there will be approximately 123 ml in the minibag.

Option 1: High Risk simulation, see Directions for Use for GroMed #GM3000.

Option 2: At this point in the test the complexity of the above procedure can be increased by transferring the entire contents of the GroMed minibag into another empty container. The receiving container, vial or bag, should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

9. **Immediately** inspect the final container contents for particulates, corings, and fibers. These particles should not be recorded as microbial growth.

10. Label the final container of TSB. For compliance with USP<797>, incubate at a temperature of 20° - 25°C or 30°-35°C for 14 days.

11. Examine the container of TSB daily for turbidity. If turbidity is observed, growth from microorganisms is indicated and the test is positive. If the TSB is clear, the test is negative and the operator has passed the test.

12. A positive test sample indicates that the operator has introduced microorganisms into the "product" and has failed the test.

13. All operators should be revalidated, using the above procedure. Frequency of revalidation depends upon risk level being simulated.

14. After 14 days, transfer piggyback label and enter related data in the GroMed log.

Q.I.medical, inc

P.O. Box 1329, Nevada City, CA 95959 (530) 265-4820 FAX (530) 265-9416

GroMed™ LOG

Test Date	Sample #	Prepared by	Hood #	Solution or Process Tested	Media Lot #	Incubation Temperature	RESULTS		
							NEGATIVE	POSITIVE	
							Initials	Organism Identified	Comments

GML001 G 6/03

ATTACHMENT C (PAGE 2)

EnviroTest™ Media Paddles

Directions for Use

Cat. #ET1000

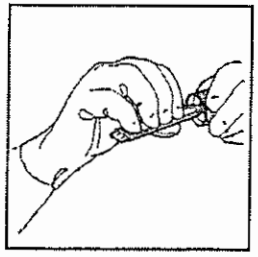


Figure 1

Glove Fingertip Sampling
Do not disinfect gloves immediately prior to sampling. Press the agar with the fingertips and thumbs of both hands in a manner to create a slight impression in the agar *(Figure 1)*.

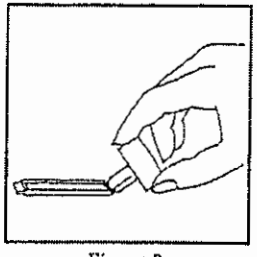


Figure 2

Contact Inoculation
Solid surfaces can be monitored for microbial contamination by pressing one side, then the other side, of the paddle firmly against the surface to be tested *(Figure 2)*. The hinged design allows full contact.
Do NOT drag the agar across the surface.

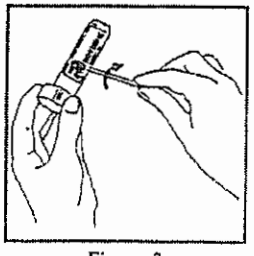


Figure 3

Swabbing
Difficult to reach surfaces can be tested by turning a sterile swab, previously moistened with sterile water, while moving across prescribed surfaces. The swab is then carefully and firmly rolled over both agar surfaces *(Figure 3)*.

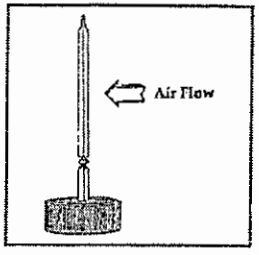


Figure 4

Impaction Air Testing
Position one of the paddle surfaces perpendicular to the air flow to be monitored, using the cap as a pedestal *(Figure 4)*. The exposure duration of the paddle to the air stream should be planned and the same each time the test is performed. Exposure longer than 2 hours may dry the agar surface.

Incubation
After inoculation or exposure, carefully replace the paddle in the vial and tightly secure the cap. Incubate at an elevated temperature (USP <797>) 30°-35°C for 48 to 72 hours.

Interpretation of Results
Carefully remove paddle from the vial and visually examine under good lighting. Count the number of discrete colonies present, if any, and report as colony forming units (cfus). Quantitative conclusions can be drawn only when using the same sampling technique under similar conditions.

EnviroTest™ - ET1000 media promotes growth of most aerobic bacteria, yeasts, and fungi.

Storage, Stability and Destruction
EnviroTest™ kits should be kept unopened at room temperature and protected from light. The paddles must not be allowed to freeze. Any unused paddles showing microbial growth should be discarded. All used paddles should be discarded in a manner consistent with applicable State and Federal regulations.

Staff Training
New or used EnviroTests can also be used to demonstrate the importance of handwashing. Press unwashed finger tips on one paddle of an EnviroTest. Wash hands and press clean finger tips on other paddle. Incubate and compare results.

TSA Media Ingredients:
Tryptose, Yeast Extract, Dextrose, Agar
Lecithin – Inactivates quaternary ammonium compounds.
Polysorbate 80 – Inactivates phenolics, hexachlorophene and formaldehyde.
Lecithin & Polysorbate 80 – synergistic effect that inactivates ethanol.

Certificate of Analysis- Available upon request

Q.I. Medical, Inc. Price List

Technical Services (800) 837-8361
E-mail: info@qimedical.com

Q.I.medical, inc
www.qimedical.com

ATTACHMENT D (PAGE 2)

EnviroTest LOG-Gloved Fingertip Sampling						RESULTS		
Test Date	Sample #	Prepared by	Hood #	Media Lot #	Incubation Temperature	Completion Date	Comments	Colony Forming Units (CFUs)

EnviroTest™ Media Paddles

Directions for Use

Cat. #ET1000

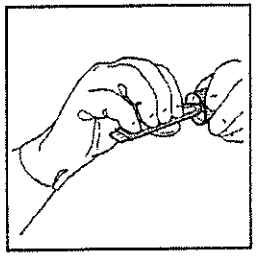


Figure 1

Glove Fingertip Sampling
Do not disinfect gloves immediately prior to sampling. Press the agar with the fingertips and thumbs of both hands in a manner to create a slight impression in the agar *(Figure 1)*.

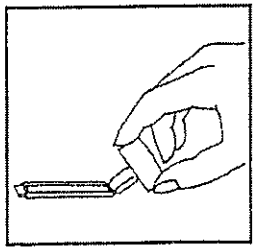


Figure 2

Contact Inoculation
Solid surfaces can be monitored for microbial contamination by pressing one side, then the other side, of the paddle firmly against the surface to be tested *(Figure 2)*. The hinged design allows full contact.
Do NOT drag the agar across the surface.

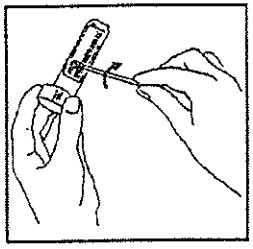


Figure 3

Swabbing
Difficult to reach surfaces can be tested by turning a sterile swab, previously moistened with sterile water, while moving across prescribed surfaces. The swab is then carefully and firmly rolled over both agar surfaces *(Figure 3)*.

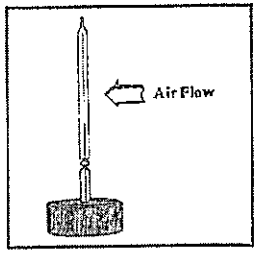


Figure 4

Impaction Air Testing
Position one of the paddle surfaces perpendicular to the air flow to be monitored, using the cap as a pedestal *(Figure 4)*. The exposure duration of the paddle to the air stream should be planned and the same each time the test is performed. Exposure longer than 2 hours may dry the agar surface.

Incubation
After inoculation or exposure, carefully replace the paddle in the vial and tightly secure the cap. Incubate at an elevated temperature (USP <797>) 30°-35°C for 48 to 72 hours.

Interpretation of Results
Carefully remove paddle from the vial and visually examine under good lighting. Count the number of discrete colonies present, if any, and report as colony forming units (cfus). Quantitative conclusions can be drawn only when using the same sampling technique under similar conditions.

EnviroTest™ - ET1000 media promotes growth of most aerobic bacteria, yeasts, and fungi.

Storage, Stability and Destruction
EnviroTest™ kits should be kept unopened at room temperature and protected from light. The paddles must not be allowed to freeze. Any unused paddles showing microbial growth should be discarded. All used paddles should be discarded in a manner consistent with applicable State and Federal regulations.

Staff Training
New or used EnviroTests can also be used to demonstrate the importance of handwashing. Press unwashed finger tips on one paddle of an EnviroTest. Wash hands and press clean finger tips on other paddle. Incubate and compare results.

TSA Media Ingredients:
Tryptose, Yeast Extract, Dextrose, Agar
Lecithin – Inactivates quaternary ammonium compounds.
Polysorbate 80 – Inactivates phenolics, hexachlorophene and formaldehyde.
Lecithin & Polysorbate 80 – synergistic effect that inactivates ethanol.

Certificate of Analysis- Available upon request

Technical Services (800) 837-8361
E-mail: info@qimedical.com

Q.I. Medical, Inc. Price List

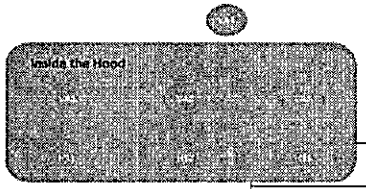
QImedical, inc

www.qimedical.com

Enviro Test LOG-Surface Testing

Test Date	Sample #	Prepared by	Hood #	Media Lot #	Incubation Temperature	RESULTS		
						Completion Date	Comments	Colony Forming Units (CFUs)

MP® ltd



Enviro Test LOG-SURFACE Testing

						RESULTS											
						30-35°C						20-25°C					
Date	Time	Technician Initial	Location	Media Lot #	Media Expiration	Incubate for minimum of 48 hours						Incubate minimum additional 5 Days					
						Date	Time	Temp	Negative	Positive CFU#	Initial Read by	Date	Time	Temp	Negative	Positive CFU#	Initial Read by

Attachment F rev 4.0

ATTACHMENT G

Med-Plus
Pharmacy LTC

FLOOR AND COUNTER TOP CLEANING LOG

MONTH/YEAR: _____ AM / PM (CIRCLE)

SOLUTIONS: _____

ALTERNATE SOLUTIONS EVERY WEEK

DATE	TIME	TECH INITIALS	RPH INITIALS	SOLUTION USED
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

ATTACHMENT H

WEEKLY CLEANING LOG

DATE:				
	WEEK 1	WEEK 2	WEEK 3	WEEK 4
CLEANING CEILING AND WIPE DOWN ALL WALLS WITH DISINFECTANT				
WIPE DOWN HOOD EXTERIORS, INCLUDING TOPS AND BASES WITH DISINFECTANT				
CLEAN DOORS, GLASS AND WALLS				
WIPE DOWN ALL CARTS, SHELVES AND CONTAINERS WITH DISINFECTANT				

	DISINFECTANTS TO BE USED:
WEEK 1:	70% ISOPROPYL ALCOHOL
WEEK 2:	CONTROL III
WEEK 3:	BLEACH (1:10)
WEEK 4:	PERIDOX (SPORICIDE)

IV DEPARTMENT DAILY TEMPERATURE LOG

Month/Year:_____

DATE	ROOM TEMPERATURE (20-25C)	CLEAN ROOM TEMPERATURE (<OR=20C)	REFRIGERATOR TEMPERATURE (2-8C)	INCUBATOR TEMPERATURE (30-35C)	INITIALS
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

INSTRUCTIONS:

Room Temperature - Indicate the temperature reading **DAILY.**
Clean Room Temperature - Indicate the temperature reading **DAILY.**
Refrigerator Temperature - Indicate the temperature reading **DAILY.**
Incubator Temperature - Indicate the temperature reading **DAILY.**
Initials - Inidcate your initials DAILY.

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of Polaris Pharmacy Services of Minnesota, LLC License No. 265679	STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

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e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY,** and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG,
Executive Director

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/02/2022)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-State	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Name Change* * If making a change, provide license #: PH _____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Seven Hills Pharmacy, LLC

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 513-771-0367 Toll Free # (NAC 639.708, NRS 639.23286): 844-643-0169

Fax: 513-771-0369 Contact Email: compliance@truepill.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Spitzer

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21780

Section 2: List all Nevada Registered Pharmacist(s) that will be Providing Pharmacy Services in/into Nevada for the pharmacy (NRS 639.100, NRS 639.015) (Use a separate piece of paper if additional space is needed.)

Name: Christopher Spitzer	NV Pharmacist Registration #: 21780
Name: Christopher Gibson	NV Pharmacist Registration #: 22645
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Seven Hills Pharmacy LLC

Mailing Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Quynh Do

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☒ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Joseph Cipriani

Print Name of Authorized Person

Joseph Cipriani

Original signature of Authorized Person (copies or stamps not accepted)

9/21/23

Date

Section 10: Affidavit for Pharmacies: MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Joseph Cipriani hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager (title) for Seven Hills Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Joseph Cipriani
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21st day of September, 2023

Patrise Bullock
Notary Public

PATRISE BULLOCK NOTARY PUBLIC WAKE COUNTY, NC

Exp. 12.12.2026

Section II: Managing Pharmacist Acknowledgement and Personal History - REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA-LICENSED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Spitzer Pharmacist Registration #: 03236754

Pharmacy Name: Seven Hills Pharmacy, LLC

Initial each statement below to indicate you have read and agree with the following:

CW I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CW I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CW I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CW I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CW I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?	✔	

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:
Written Reprimand and Penalty	Ohio	3/9/2022	A-2021-0336

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A					

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

12/7/22
Date

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partnership	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** o **All General Partners;** o **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing from** the Secretary of State's Office where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Designated Representative Form** http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.		✓	✓	✓
• **Personal History Record Application** http://bop.nv.gov/Services/newapps/Business/ must be completed by: a. **For Non-publicly traded** - The top 4 shareholder/stockholders. b. **For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. c. **For Sole Owner** - The owner.		✓	✓	✓
• **Sterile Compounding Questionnaire** must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	✓	✓	✓
• **Submit a copy of your most recent pharmacy inspection** from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f)	✓	✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your pharmacy** from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a)	✓	✓	✓	✓
• **License Verification** by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g)	✓	✓	✓	✓
• **Copy of DEA Registration if handling controlled substances (REQUIRED FOR NON-NEVADA PHARMACIES ONLY)**	✓	✓	✓	✓
• **Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)**	✓	✓	✓	✓
• **Transmit Controlled Substance Prescription Data**- Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Cipriani

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/21/23

Date

Board Use Only	Date Received: 9/27/23	Amount:

List of Managers

1) Paul Greenall – Manager – DOB: [redacted] - [redacted] Benjamin Way, Healdsburg, CA 95448

2) Joseph Cipriani – Manager - DOB: [redacted] - [redacted] Lorraine RD, Raleigh, WA 27607

Truepill
KS license 22-117859
DEA license FP6189725
AL license 114861

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy a Consent Order of Discipline dated June 6, 2023. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

DEA Order to Show Cause
Although the matter remains pending and no discipline has issued, for transparency with the Board and out of an abundance of caution, the Pharmacy wishes to disclose that on December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued the Pharmacy an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. On January 13, 2023, the Pharmacy answered the OSC.

Kansas Board of Pharmacy
The Kansas Board of Pharmacy issued the pharmacy an amended Summary Order effective February 8, 2023. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	**BOARD OF PHARMACY**
	)	
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By:
Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

50949995 v1

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

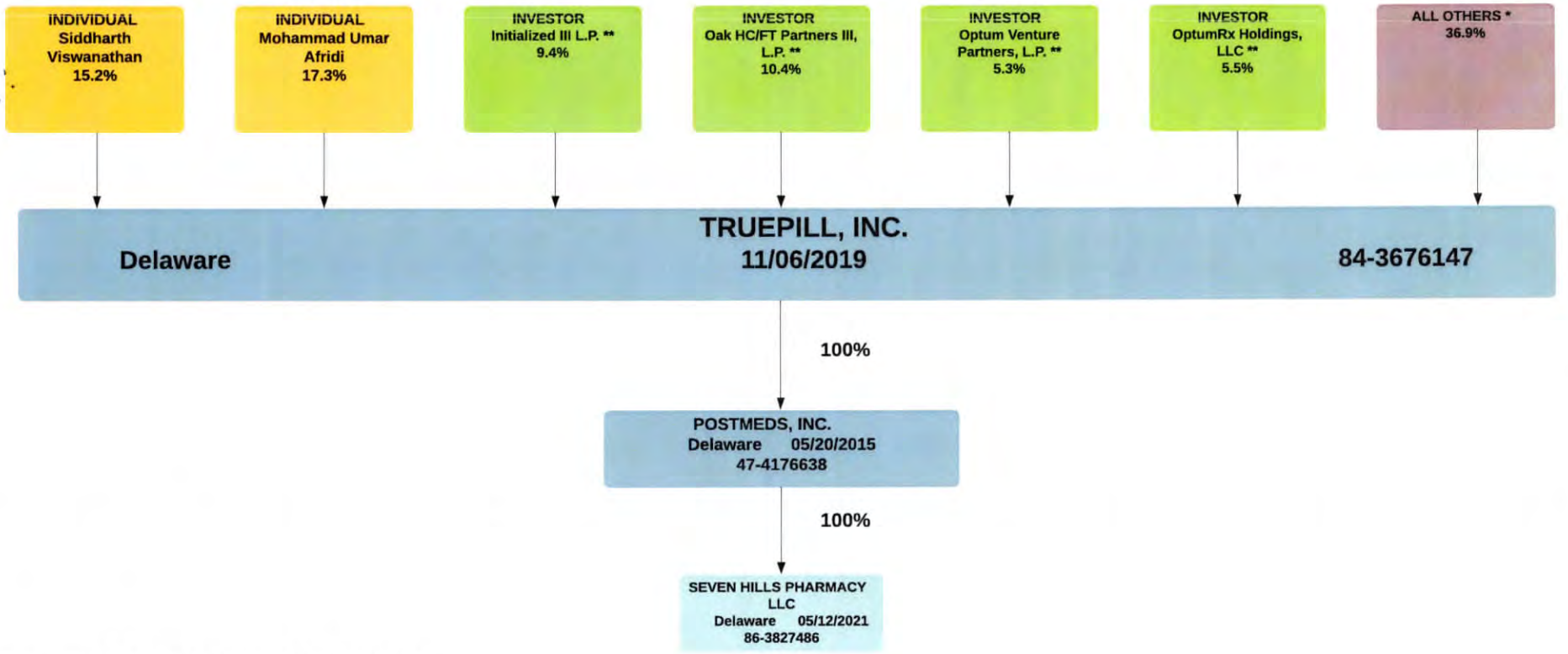
Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

Nov 3, 2021 10:06 AM

Seven Hills Pharmacy - Board of Pharmacy ONLY

CONFIDENTIAL! DO NOT DISTRIBUTE TO THIRD PARTIES



*No individual/entity in this group owns > = 3% of Truepill, Inc., and therefore no individul/entity in this group owns > = 5% of the Provider

**No individual owns >= 5% of Truepill, Inc., and therefore no individual/entity in this group owns > = 5% of the Provider

Corporation | Limited Liability Company | Investor | Individual | Other

This organizational chart was prepared by the Legal Team & contains entity name, state of domicile, date of formation & EIN.
For additional details, please contact entities@truepill.com

List of Managers

Name	Title	Business Address	Home Address	Business Phone	Home Phone	SSN	DOB
Daniel Simkin	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted] Hyperion Ave, Los Angeles, CA 90029	650-353-5495	[redacted]	[redacted]	[redacted]
Siddharth Viswanathan	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted]Long Bridge Street, Apt 514, San Francisco, CA 94158	650-353-5495	[redacted]	[redacted]	[redacted]
Mathew Davis-Ratner	Manager	3121 Diablo Ave, Hayward, CA 94545	[redacted]51st Ave S, Seattle, WA 98118	650-353-5495	[redacted]	[redacted]	[redacted]

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show SEVEN HILLS PHARMACY LLC, a Delaware Limited Liability Company, Registration Number 4684707, was registered in the State of Ohio on May 24, 2021, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 11th day of October, A.D. 2022.

Ohio Secretary of State

Validation Number: 202228404922

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0232000312

Seven Hills Pharmacy Llc

2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Terminal - Pharmacy - Category 3

Outpatient Pharmacy Inspection

November 7, 2022

License 0232000312 - Seven Hills Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Sharon Shields
Start 11/7/2022 9:06 AM
End 11/7/2022 11:48 AM

Organization

Name
Seven Hills Pharmacy Llc

License Type
Terminal - Pharmacy - Category 3

Category

License Number
0232000312

Business Type
II - Independent Community Retail (1 Outlet)

DEA Number

Responsible Person
Christopher Spitzer, R.Ph.

Hours of Operation
M-F 9a-5p; Sat/Sun closed

Contact

Address
[redacted] E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Primary Number
[redacted]

Fax Number
(513) 771-0369

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Christpoher Gibson, R.Ph.		Pharmacist	03236967		
Lisa Beth Klein		Certified Pharmacy Technician	09305487	[redacted]	[redacted]
Christopher Spitzer, R.Ph.		Responsible Person	03236754		

1) Initial Inspection Information

3) What is the name and current version of the dispensing software being used by the pharmacy?

Observation
Pharmacy uses both Pioneer and TruePill operating system. Operating systems are client specific in their use. Pharmacy is phasing out use of Pioneer.

5) Facility description

Observation
Facility is a retail pharmacy servicing the patients of various online prescriber entities. Pharmacy has the ability to serve the community (walk-in patient). Pharmacy does not accept insurance. Pharmacy has limited drug stock. Pharmacy processes approximately 150 prescriptions per day. Pharmacy employs two pharmacists and one certified pharmacy technician. Pharmacy ships prescriptions to patients in Ohio and in other states using USPS, UPS, and FedEx.

2) * Licensing, Responsible Person and DEA Registration

1) Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

2) Does the responsible person match what is indicated in eLicense?

Yes

3) Does the pharmacy have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
FS1293884 expires 2/28/2025

3) * Minimum Standards

1) Does the pharmacy have internet access to current federal and state laws, regulations, and rules governing the legal distribution of drugs in Ohio?

Yes

2) Does the pharmacy have access to the telephone number of a poison control center?

Yes

3) Are the pharmacy's hours publicly posted?

Yes

4) Are all pharmacy staff wearing name tags/badges that include the employee's job title?

Yes

7) Are the library and equipment housed in a suitable, well-lit and well-ventilated room or department and maintained in a clean, sanitary and orderly condition?

Yes

8) Are areas where drugs and devices are stored and prepared dry, well-lit, well-ventilated, and maintained in a clean, sanitary and orderly condition?

Yes

9) Are storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?

Yes

4) Personnel

1) Are staff working at the pharmacy properly licensed/registered with the Board?

Yes

5) Are certified pharmacy technicians working within their applicable scope of practice?

Yes

8) Are pharmacy support personnel working within their permitted scope?

Not Applicable - No support personnel working or employed during inspection.

Observation
List of support personnel responsibilities: www.pharmacy.ohio.gov/supportres

OAC 4729:3-1-01 (Z)
(1) An individual employed or performing contracted services at a location licensed as a terminal distributor of dangerous drugs, trained to perform clerical duties associated with the practice of pharmacy, including pricing, cashiering, drug purchasing, delivering, scheduling deliveries, answering non-professional telephone inquiries, transportation of dispensed medications within a hospital, documenting and processing third-party billing information for reimbursement, or any other activity as determined by the board.

(2) An individual contracted by a terminal distributor of dangerous drugs to perform drug inventories.

(3) Except for those responsible for the delivery of dangerous drugs, support personnel shall not have unsupervised access to dangerous drugs.

(4) Support personnel shall not perform the tasks of a pharmacist, pharmacy intern, certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee.

(5) Support personnel may have access to or retrieve information from patient records, including a database or patient profile to perform clerical duties associated with the practice of pharmacy. Support personnel shall not enter prescription information into a patient profile.

(6) Support personnel may perform the following:

(a) Transporting dangerous drugs from a loading dock, warehouse or other area that receives shipments from a licensed wholesaler or other person licensed in accordance with section 4729.52 of the Revised Code; and

(b) Stocking and retrieving from inventory non-controlled dangerous drugs that are not dispensed by the pharmacy.

(7) The terminal distributor of dangerous drugs shall be responsible for ensuring all support personnel comply with state and federal requirements to ensure the confidentiality of patient health records.

(8) Stocking of automated drug dispensing units and floor stock with intravenous fluids that are non-controlled dangerous drugs and are not dispensed by an institutional pharmacy.*

(9) Overwrapping/placing in plastic dangerous drugs that have been compounded or dispensed (i.e. appropriately labeled) by a terminal distributor of dangerous drugs.*

(10) Entering demographic and insurance information into a patient's profile.*

10) Drug Purchases

1) Does the licensee maintain complete and accurate records of drugs purchased?

Yes

Observation
Wholesalers:

- McKesson
- TopRx
- Keysource
- Anda

2) Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?

Yes

11) * Security, Control, and Storage of Dangerous Drugs

1) Is a pharmacist providing supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs in the pharmacy?

Yes

3) Are all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control?

Yes

4) Are there any unauthorized persons present in the pharmacy?

No

7) Can the pharmacy be secured by a physical barrier or alarm system?

Yes

Observation
The only change to the barricade since March 2022 inspection was the replacement of the garage-style door. Door was replaced with a metal roll down bay-style door. Door is secured by the alarm system. No other changes to the barricade have been made since inspection in March 2022. Barricade is adequate.

8) Is a licensed pharmacist the only person with access to keys or other methods for accessing the pharmacy?

Yes

10) Does the pharmacy have a secure area only accessible by pharmacists for customers to deposit new or refill prescription orders when the pharmacy is closed?

No - Not applicable

11) Does the pharmacy maintain dangerous drugs or hypodermics outside of the confines of the pharmacy?

No

12) Does the pharmacy provide services by means of a secured drive-through facility?

No

12) Temperature Controls

1) Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?

Yes

Observation
Pharmacy has one refrigerator for vaccine storage. Pharmacy uses TempAlert to monitor the temperature of the refrigerator. Observed refrigerator to be at appropriate temperature. Pharmacy does not have vaccine stock or any refrigerator/freezer drug stock on site at the time of inspection.

2) Does the pharmacy have a policy to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs?

Yes

3) Are refrigerators and freezers use for the storage of drugs free of food or beverage products?

No

13) *Theft or Significant Loss of Drugs and Drug Documents

1) Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

3) REMINDER: Theft or significant loss of dangerous drugs and drug documents.

Observation
REMINDER

A licensee is required to report to the the Board and law enforcement authorities of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor.

A licensee is required to report, immediately upon discovery, to the Board and law enforcement authorities any theft or loss of uncompleted prescription blank(s) used for writing a prescription, D.E.A. controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

14) * Controlled Substance Inventory

1) Does the licensee conduct an annual inventory of controlled substances?

Yes

Observation
Pharmacy does not have any controlled substance drug stock on site at the time of inspection.
OAC 4729:5-3-07
All Category III licensees must complete an annual inventory even if drugs are not on-site (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process for conducting a DEA controlled substance inventory.

16) Drug Collection Receptacles

1) Does the pharmacy operate a drug take back program (i.e. collection receptacle)?

No

17) Drug Samples

1) Does the pharmacy have sample drugs as part its inventory?

No

23) Return to Stock

4) Does the pharmacy use delivery agents?

Yes - Compliant

Observation
Pharmacy uses USPS, UPS, and FedEx. Pharmacy does not return any delivered drugs back to stock for redispensing. All drug stock returned from delivery agents are sent to Inmar for destruction.

8) REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.

Observation
REMINDER: The contents of a prescription vial or container shall not be returned to the manufacturer's stock bottle.
OAC 4729:5-5-22 (B)(4)

25) Customized Medication Packaging (Adherence Packaging)

1) Does the pharmacy dispense customized patient medication packages (sometimes referred to as adherence packaging)?

No

27) Charitable Pharmacies

1) Is this pharmacy a charitable pharmacy?

No

31) *Expired/Adulterated Drugs

2) Are there expired/adulterated drugs present in the licensee's active drug stock?

No

33) Prescription Pick-Up Station

1) Does the pharmacy accept prescriptions from pick-up stations or other intermediaries?

No

39) Drug Repository Program

1) Does this pharmacy operate a drug repository program?

No

40) Temporary Removal of Drugs

1) Does the licensee engage in the temporary off-site storage of dangerous drugs?

No

46) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient.
These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Boar of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (the resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health srevices.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

50) Inspection Affirmation

1) Inspection Affirmation

Observation

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:

(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to writtenresponse@pharmacy.ohio.gov or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Christopher Spitzer, R.Ph. _____

(signature)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FS1293884	02-28-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-23-2022

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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Form DEA-223 (9/2016)

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	**Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination**	**Citation without a fine**
Bus. & Prof. Code § 4174	**Dispensing on order of nurse practitioner or person of similar status.**	**Citation without a fine**

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	**TOTAL AMOUNT OF FINE(S): $0.00**

PAYMENT OF FINE(S) DUE BY: July 16, 2020

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
[redacted] DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
[redacted] DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021

TOTAL AMOUNT OF FINE(S): $5,000.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021

COPY

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

svb

Silicon Valley Bank

3003 Tasman
Santa Clara, California 95054
408-654-7400

90-4039
1211

CASHIER'S CHECK No. 208457

Date	Check No.	Amount
Apr 13,2022	208457	$10,574.80

Remitter: **Postmeds, Inc.**
Permit No. 7761

PAY EXACTLY
*** **Ten Thousand Five Hundred Seventy-Four and 80/100** **Dollars**

TWO SIGNATURES REQUIRED OVER $50,000.00

Pay to the order of: **Louisiana Board of Pharmacy**

⑈208457⑈ ⑆121140399⑆ [redacted]⑈

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS**:

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

Truepill
CA old license PHY 56100
ME old license MO40002429
NC old license 13413
LA license PHY.007761-NR
KS license 22-117859
DEA license FP6189725

DEA Order to Show Cause
Although the matter remains pending and no discipline has issued, for transparency with the Board and out of an abundance of caution, the Pharmacy wishes to disclose that on December 15, 2022, the federal Drug Enforcement Agency ("DEA") issued the Pharmacy an administrative Order to Show Cause ("OSC") regarding revocation of its DEA registration FP6189725. On January 13, 2023, the Pharmacy answered the OSC.

Kansas Board of Pharmacy
The Kansas Board of Pharmacy issued the pharmacy an amended Summary Order effective February 8, 2023. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy
The Louisiana Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated May 11, 2022. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated March 8, 2022. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on March 30, 2022 that its non-resident license was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy a letter of admonishment CI 2019 84877 dated January 23, 2020, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy a modified citation and fine CI 2019 78633 dated June 16, 2020, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy

by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy a citation and fine order of abatement CI 2020 89223 dated August 25, 2021, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

U.S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Springfield, Virginia 22152

IN THE MATTER OF

Truepill
3121 Diablo Ave
Hayward, CA 94545

DEA Certificate of Registration FP6189725

ORDER TO SHOW CAUSE

Telemedicine is an important tool for providing increased access to medical treatment that has been relied upon by hundreds of millions of Americans since the onset of the COVID-19 pandemic in 2020. Unfortunately, this access is being exploited by a subset of medical practitioners and businesses seeking opportunities to profit by wrongfully providing controlled substances without a legitimate medical purpose.

DEA has an obligation to protect the public by ensuring that pharmacists only fill prescriptions for controlled substances which are prescribed for legitimate medical purposes by practitioners acting in the usual course of professional practice. It is critical that entities engaged in the practice of online pharmacy are appropriately registered and subject to reporting, disclosure, and other requirements imposed under law. These requirements allow entities engaged in the legitimate practice of telemedicine to continue safely providing critical services and protect the safety and health of the American public.

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) and its implementing regulations prohibit actors from operating as an "online pharmacy" without the appropriate DEA registration. Truepill does not have the requisite registration to act as an online pharmacy. But since September 2020, it has acted as an online pharmacy, and in a two-year period filled 72,000 controlled substance prescriptions, of which 60% were for stimulants, such as amphetamines used in the treatment of Attention Deficit/Hyperactivity Disorder (ADHD).

Truepill was the pharmacy for telehealth companies, including Cerebral, that marketed ADHD treatments, including Adderall ® and its generic forms, directly to consumers using Internet advertisements and social media. Cerebral arranged for patients to receive prescriptions for ADHD treatments through a telehealth visit, and for Truepill to fill those prescriptions. In numerous instances, Truepill dispensed controlled substances pursuant to prescriptions that were not issued for a legitimate medical purpose in the usual course of professional practice. Many of these prescriptions were written by providers that lacked the requisite state certifications to prescribe and who issued multiple prescriptions for a patient to receive more than a 90-day supply of a

Schedule II controlled substance, including prescriptions for the treatment of ADHD, in violation of federal regulations.

Accordingly,

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Truepill an opportunity to Show Cause before the Drug Enforcement Administration (DEA), at the DEA Hearing Facility, 700 Army Navy Drive, 2nd Floor, Arlington, Virginia 22202, or a location designated by the Administrative Law Judge, on March 21, 2023, or on such a subsequent date designated by the Administrative Law Judge (if Truepill requests such a hearing), as to why DEA should not revoke Truepill's DEA Certificate of Registration (COR or registration), Number FP6189725, pursuant to 21 U.S.C. § 824(a)(4), and deny any applications for any other DEA registrations, because Truepill's registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f).

As detailed below, this Order states DEA's basis to revoke the above-referenced DEA registration, including a ***non-exhaustive summary*** of the matters of fact and law at issue, as well as citations to laws and regulations that Truepill has violated (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia*). In order to preserve Truepill's rights in this proceeding, Truepill may appear in these revocation proceedings by filing a notice of appearance or request for hearing in the manner prescribed by regulations within 30 days from the receipt of this Order. On or before the date of Truepill's appearance, Truepill may submit a corrective action plan that will be considered by DEA in accordance with 21 U.S.C. § 824(c).

LEGAL REQUIREMENTS

Entities That Must Register as Online Pharmacies

Federal law proscribes any person from distributing or dispensing a controlled substance except as authorized by the Controlled Substances Act (CSA). *See* 21 U.S.C. §§ 841(a)(1); 842(a)(1). Federal law further explicitly provides that it is unlawful for "any person" to "deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized" by the CSA. 21 U.S.C. § 841(h)(1).

An "online pharmacy" is "a person, entity, or Internet site . . . that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet." 21 U.S.C. § 802(52)(A); *see also* 21 C.F.R. § 1300.04(h) (same). Further, the term "'deliver, distribute, or dispense by means of the Internet' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet." 21 U.S.C. § 802(51). To act as an online pharmacy, a pharmacy must "request that the Administrator modify its registration to authorize the pharmacy to dispense controlled substances by means of the Internet as an online pharmacy." 21 C.F.R. § 1301.19(a); *see* 21 C.F.R. § 1301.11(b).

The CSA instructs that "it is unlawful for any person who falls within the [CSA's] definition of 'online pharmacy' . . . to deliver, distribute, or dispense a controlled substance by means of the

Internet" unless that person is "validly registered with a modification of such registration authorizing such activity." 21 C.F.R. § 1301.11(b). "Accordingly, any pharmacy registered" with DEA "that falls within the definition of an online pharmacy and proposes to dispense controlled substances by means of the Internet must obtain a modification of its registration authorizing such activity." *Id.*; *see also* 21 C.F.R. § 1301.19(f) ("No person . . . required to obtain a modification of a registration . . . authorizing it to operate as an online pharmacy may engage in any activity for which such modification of registration is required until the application for such modified registration is granted and an active Certificate of Registration indicating the modification of the registration has been issued by the Administrator to such person."). The CSA explicitly provides that "delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity" is a violation of section 841(h)(1). 21 U.S.C. § 841(h)(2)(A).

Requirements Applicable to Online Pharmacies

An online pharmacy is subject to a number of requirements under the CSA. Among other things, an online pharmacy must:

- "[D]isplay in a visible and clear manner on its homepage a statement that it complies with the requirements of this section with respect to the delivery or sale or offer for sale of controlled substances." 21 U.S.C. § 831(a); 21 C.F.R. § 1304.45(a); *see also* 21 U.S.C. § 802(53) ("The term 'homepage' means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.").

- Post "in a visible and clear manner" on its homepage or a page clearly linked from its homepage, the following information:

    - "The name, professional degree, and States of licensure of the pharmacist-in-charge, and a telephone number at which the pharmacist-in-charge can be contacted."

    - "A list of the States in which the pharmacy is licensed to dispense controlled substances."

    - "A certification that the pharmacy is registered under" the CSA "to deliver, distribute, or dispense" controlled substances "by means of the Internet."

    - The following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in

accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54))."

See 21 U.S.C. § 831(c); 21 C.F.R. § 1304.45.

- Notify the DEA Administrator, thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing, of, among other things: the information the online pharmacy is required to post on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45; each Internet site address used by the online pharmacy; the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites; and a certification that the information provided on its Internet site under 21 U.S.C. § 831(c), and 21 C.F.R. § 1304.45 is true and accurate. *See* 21 U.S.C. § 831(d); 21 C.F.R. § 1304.40(b).

- Display on its homepage a declaration that it has made an appropriate notification to the DEA Administrator. *See* 21 U.S.C. § 831(e); 21 C.F.R. § 1304.40(d).

- Monthly report to the DEA Administrator of the total quantity of controlled substances the online pharmacy has dispensed for each calendar month in which it dispenses either 100 or more controlled substance prescriptions, or 5,000 or more dosage units of controlled substances. If the pharmacy's dispensing does not meet either threshold in a given month, it must report a negative response for that month. *See* 21 C.F.R. § 1304.55.

Requirements Applicable to All Pharmacies

A "prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. A pharmacist is only permitted to fill prescriptions "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Although "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, . . . a corresponding responsibility rests with the pharmacist who fills the prescription." *Id.*

"DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when [s]he either knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Wheatland Pharmacy*, 78 Fed. Reg. 69,441, 69,445 (2013) (internal quotation marks and citation omitted, alternation in original). Section 1306.04(a) "expressly requires pharmacists to identify and resolve suspicions that a prescription is illegitimate." *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7331 (2018).

A violation of these regulations is a violation of federal law. *See* 21 U.S.C. § 842(a)(1) (making it unlawful to dispense controlled substances in violation of 21 U.S.C. § 829, whose scope is defined in part by 21 C.F.R. §§ 1306.04, 1306.06). Any attempt to violate these regulations is also a violation of federal law. *See* 21 U.S.C. § 846.

Additionally, DEA may find that a registrant's DEA COR is inconsistent with the public interest if the registrant acted carelessly or negligently in handling controlled substances, even if the registrant did not intend to violate the Controlled Substances Act. *See, e.g., Med. Shoppe*, 79 Fed. Reg. 59,504, 59,506 (2014) ("Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify revocation or denial." (quoting *Paul J. Caragine, Jr.*, 63 Fed. Reg. 51,592, 51,601 (1998))).

Pharmacies are also required to keep appropriate records as set forth in the CSA. "Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances." *Wayne Pharmacy*, 85 Fed. Reg. 63,579, 63,582 (2020). Such recordkeeping is one of the central features of the CSA's regulatory regime because "a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances." *Superior Pharmacy I & Superior Pharmacy II*, 81 Fed. Reg. 31,310, 31,337 (2016). Thus, a finding that a registrant "failed to maintain complete and accurate records . . . supports the conclusion that [the registrant] has committed such acts as to render its continued registration 'inconsistent with the public interest.'" *Id.* at 31,338 (quoting 21 U.S.C. § 824(a)(4)).

Pharmacies are also required to, among other things, "maintain, on a current basis, a complete and accurate record of each [controlled] substance . . . received, sold, delivered, or otherwise disposed of." 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a); *see also* 21 C.F.R. § 1304.22(c) (specific recordkeeping requirements for dispensers).

An individual practitioner is not authorized, on a single occasion, to issue multiple prescriptions for a patient to receive more than a 90-day supply of a Schedule II controlled substance. *See* 21 C.F.R. § 1306.12(b).

State of California Authority to Dispense Controlled Substances

As noted above, a pharmacy may only fill valid prescriptions. *See* 21 U.S.C. § 829; 21 C.F.R. § 1306.06.

California law provides that to practice as a nurse practitioner in California, a nurse practitioner must hold, among other things, a valid and active registered nursing license issued by the Board of Registered Nursing (Nursing Board). Cal. Bus. & Prof. Code § 2835.5. Additionally, for a nurse practitioner licensed in California to prescribe a controlled substance, the Nursing Board must certify that the nurse practitioner satisfactorily completed a course in pharmacology covering the controlled substances to be prescribed and must issue a Furnishing Number to the nurse practitioner. *See id.* §§ 2836.1(g)(1), 2836.2, 2836.3.

To practice as a doctor of naturopathic medicine in California, one must hold a valid and active naturopathic medicine license issued by the California Naturopathic Medicine Committee. *See* Cal. Bus. & Prof. Code §§ 3630, 3633, 3644(d)(2). Schedule III through V controlled substances may only be dispensed by a naturopathic doctor under supervision by a physician or surgeon and pursuant to standardized procedures or protocols established between them. *See* Cal. Bus. & Prof. Code § 3640.5(f).

To practice as a physician assistant in California, one must hold a valid physician assistant license issued by the California Physician Assistant Board. *See* Cal. Bus. & Prof. Code § 3519;

see also Cal. Bus. & Prof. Code §§ 3501, 3503, 3516. Schedule II through V controlled substances may only be prescribed by a physician assistant under supervision by a physician or surgeon and pursuant to a practice agreement. *See* Cal. Bus. & Prof. Code §§ 3502.1 and 3516.

Additionally, practitioners licensed outside California may only be authorized to practice within California by the California Director of Emergency Medical Services Authority during a gubernatorially declared state of emergency. *See* Cal. Bus. and Prof. Code § 900.

BACKGROUND

1. Truepill is registered as a retail pharmacy under DEA COR Number FP6189725 in Schedules II through V with a registered address of 3121 Diablo Avenue, Hayward, California 94545. Truepill's registration expires by its own terms on November 30, 2025.

2. Truepill is not registered as an online pharmacy with DEA.

3. Truepill is licensed by the State of California as a community pharmacy with license number PHY58585. Truepill's pharmacy license expires by its own terms on March 1, 2023.

4. Between on or about September 14, 2020, and September 13, 2022, of the more than 72,000 controlled substances Truepill filled, nearly 46,000 were stimulants, accounting for more than 60% of the controlled substances Truepill dispensed.

5. Truepill's DEA COR should be revoked, and any applications for registration should be denied, because Truepill has committed such acts as would render its registration inconsistent with the public interest. *See* 21 U.S.C. §§ 823(f), 824(a)(4). Specifically, Truepill has acted as an online pharmacy without obtaining an appropriate DEA registration and without meeting a number of legal requirements applicable to online pharmacies. Truepill has, on numerous occasions, unlawfully filled controlled stimulant prescriptions issued by prescribers with no state authority to issue such prescriptions. Truepill has also repeatedly filled controlled stimulant prescriptions there were for more than a 90-day supply, in violation of 21 C.F.R. § 1306.12(b).

6. Dextroamphetamine-amphetamine, which is often sold under the brand names Adderall® and Adderall XR®, is a Schedule II stimulant.

7. Methylphenidate, which is often sold under the brand name Ritalin®, is a Schedule II stimulant.

OPERATING AS AN ONLINE PHARMACY WITHOUT DEA REGISTRATION

8. Truepill provides both pharmacy and technical services to corporate customers, including telehealth companies such as Cerebral. Moreover, Truepill employs a number of customer service representatives to assist its corporate customers.

9. On its Internet site, Truepill describes itself as a "virtual pharmacy," providing "[a]n end-to-end virtual pharmacy experience." Furthermore, Truepill claims that "Truepill's virtual pharmacy enables you to create the convenient experience your customers want."

10. Truepill provides its corporate customers with a software platform containing, among other things, patient information, prescriber information, and prescription information to facilitate the delivery of prescriptions by means of the Internet.

11. Truepill's Internet site also extensively describes how its software programs assist its corporate customers in providing patients with prescriptions. Among other things, the Truepill's Internet site includes the following statements:

    a. Truepill states that it can help companies "[d]eliver medications to your patients using powerful programmatic APIs [Application Programing Interfaces] that give you full control." It further states that these companies can "[p]air our pharmacy fulfillment services with our telehealth solutions to make your programs more accessible to patients who may find it difficult to commute to a doctor's office."

    b. Truepill informs that it provides other software that uses the Internet to facilitate the filling of prescriptions, including, among others, telehealth APIs to help practitioners create and update patient records, and to provide the practitioners' patients with patient health questionnaires, all in "the Truepill ecosystem." Truepill makes clear that its telehealth API customers are "third-party provider networks and physician groups that that can diagnose, treat and prescribe for your patient population. These providers are all part of licensed professional medical corporations who are independently owned and operated."

    c. Truepill explains that it uses a "fulfillment API" to assist providers to "efficiently get medications to your patient's door across all 50 states." Truepill goes on to explain how its software platform uses the Internet to electronically create patient records, obtain prescriptions, and allow practitioners to create fill requests that they submit to Truepill electronically.

    d. Truepill states that it offers a "team of marketers, merchandisers, and fulfillment experts" to help telehealth companies "maximize the value of your e-commerce program."

12. Through these services, Truepill "deliver[ed], distribute[ed], or dispense[ed]" "a controlled substance by means of the Internet," despite not being registered as an online pharmacy, in violation of 21 U.S.C. § 841(h)(1) and 21 C.F.R. §§ 1301.11(b) & 1301.19(f).

FAILURE TO MAKE AND DISPLAY REQUIRED REPORTS AND NOTIFICATIONS

13. Despite operating as an online pharmacy, Truepill failed to put on its Internet site information required by the CSA, including:

a. A statement on its homepage that Truepill complies with the requirements of 21 U.S.C. § 831 with respect to the delivery or sale or offer for sale of controlled substances, in violation of 21 U.S.C. § 831(a) and 21 C.F.R. § 1304.45(a).

b. A visible and clear statement on its homepage, or a page clearly linked from its homepage including:

   i. the name, professional degree, and states of licensure of its pharmacist-in-charge;

   ii. a telephone number at which its pharmacist-in-charge can be contacted;

   iii. a list of states in which Truepill is licensed to dispense controlled substances;

   iv. a certification that Truepill is licensed under the CSA to deliver, distribute, or dispense controlled substances by means of the Internet; and

   v. the following statement: "This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. 829) or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. 802(54)).";

all in violation of 21 U.S.C. § 831(c) and 21 C.F.R. § 1304.45.

14. Truepill failed to notify the DEA Administrator of the information listed in 13.b., *supra*, through the submission of an application for a modified registration thirty days before offering a controlled substance for sale, delivery, distribution, or dispensing together with a certification that such information is true and accurate, in violation of 21 U.S.C. § 831(d) and 21 C.F.R § 1304.40(a)(1). Truepill also did not notify the DEA Administrator of each Internet site address it used, nor of the DEA registration numbers of every pharmacy that delivers, distributes or dispenses controlled substances pursuant to orders made through each of those identified websites, in violation of 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b)(3) and (4).

15. Truepill failed to display on the homepage of its Internet site that it had made an appropriate notification to the DEA Administrator under 21 U.S.C. § 831(d) and 21 C.F.R. § 1304.40(b), in violation of 21 U.S.C. § 831(e) and 21 C.F.R. § 1304.40(d).

16. Truepill failed to the provide the DEA Administrator with any of the monthly reports required by 21 C.F.R. § 1304.55.

UNLAWFUL DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS FOR GREATER THAN 90-DAY SUPPLY

17. Between on or about September 13, 2020, and September 13, 2022, in dozens of instances, Truepill dispensed Schedule II controlled substances for prescriptions written on a single date by an individual practitioner to an individual patient for a greater than 90-day supply. A non-exhaustive set of examples is provided below.

18. On August 24, 2020, a practitioner issued **Patient N.S.** five prescriptions amounting to a 150-day supply of dextroamphetamine-amphetamine extended release (ER) 10 mg capsules, which are often sold under the brand name Adderall XR®, a total of 300 capsules, which Truepill dispensed.

19. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate 20 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

20. On January 12, 2021, a practitioner issued **Patient L.H.** four prescriptions amounting to a 120-day supply of methylphenidate ER 54 mg tablets, which are often sold under the brand name Ritalin®, a total of 120 tablets, which Truepill dispensed.

21. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 20 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

22. On February 11, 2021, a practitioner issued **Patient D.K.** two prescriptions amounting to a 180-day supply of dextroamphetamine-amphetamine ER 30 mg capsules, which are often sold under the brand name Adderall XR®, a total of 180 capsules, which Truepill dispensed.

23. On March 9, 2021, a practitioner issued **Patient H.M.** three prescriptions amounting to a 210-day supply of dextroamphetamine-amphetamine 10 mg tablets, which are often sold under the brand name Adderall®, a total of 315 tablets, which Truepill dispensed.

24. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine ER 15 mg capsules, which are often sold under the brand name Adderall XR®, a total of 120 capsules, which Truepill dispensed.

25. On November 8, 2021, a practitioner issued **Patient N.B.** four prescriptions amounting to a 120-day supply of dextroamphetamine-amphetamine 5 mg tablets, which are often sold under the brand name Adderall®, a total of 120 tablets, which Truepill dispensed.

UNLAWFUL DISPENSING OF CONTROLLED SUBSTANCES PURSUANT TO PRESCRIPTIONS ISSUED BY PRACTITIONERS WITHOUT STATE AUTHORITY

26. Between on or about September 13, 2020, and September 13, 2022, Truepill dispensed controlled substances to patients located in California pursuant to prescriptions written by numerous practitioners who were neither sufficiently licensed in California to do so nor holders of an Authorization for Out-of-State Health Care Practitioner issued by the California Emergency Medical Services Authority (Temporary Emergency Authorization). These practitioners included nurse practitioners, physician assistants, and doctors of naturopathic medicine.

27. A non-exhaustive set of insufficiently licensed practitioners who also did not hold a Temporary Emergency Authorization include: **Nurse Practitioner N.B.**; **Nurse Practitioner T.C.**; **Nurse Practitioner D.S.**; **Nurse Practitioner H.M.**; **Nurse Practitioner J.M.**; **Nurse Practitioner A.N.**; **Nurse Practitioner S.O.**; **Nurse Practitioner A.S.**; and **Nurse Practitioner N.S.**

RECORDKEEPING AND AUDIT FINDINGS

28. In September and October of 2022, DEA investigators conducted an audit of Truepill's controlled substance records by conducting an inventory of certain controlled substances present at Truepill's registered location and comparing that inventory to the records maintained and provided by Truepill. DEA's audit identified 1,674 missing dosage units of dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was unable to account, in violation of 21 C.F.R. §§ 1304.21(a) and 1304.22(c). *See Bill Lloyd Drug*, 64 Fed. Reg. 1,823, 1,824 (1999) ("The shortages and overages revealed by the accountability audit show that Respondent does not keep complete and accurate records of its controlled substance handling as required by 21 U.S.C. 827 and 21 CFR 1304.21.").

29. This shortage of 1,674 units constituted over two percent of the dextroamphetamine-amphetamine ER 20 mg, often sold under the brand name Adderall XR®, for which Truepill was accountable during the audit period. Truepill's failure to account for a significant number of dosage units of controlled substances not only violated its obligation to maintain accurate records, but also constituted a failure to comply with its obligation to maintain effective controls against the diversion of controlled substances into illicit channels. *See, e.g.*, *Superior Pharmacy*, 81 Fed. Reg. at 31,337.

THE following procedures are available to Truepill in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Truepill fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Truepill may file with DEA a waiver of hearing together with a written statement regarding its position on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Truepill decline to file a request for a hearing, or should Truepill request a hearing and then fail to appear at the designated hearing, Truepill shall be deemed to

have waived the right to a hearing, and DEA may cancel such hearing and may enter a final order in this matter without a hearing based upon the evidence presented. *See* 21 C.F.R. §§ 1301.43(d), 1301.43(e).

Requests for hearing should be filed by email with the Office of Administrative Law Judges at the following address: ECF-DEA@dea.gov, with a copy simultaneously provided to the Government at the following address: DEA.Registration.Litigation@dea.gov. Except as provided below with respect to a corrective action plan, correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. A copy of the same shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45.

OPPORTUNITY TO SUBMIT CORRECTIVE ACTION PLAN

In addition to the procedural options set forth in paragraphs 1 and 2 above, in accordance with 21 U.S.C. § 824(c)(2)(C), Truepill has the opportunity to submit a corrective action plan, which must be received by the Acting Assistant Administrator, Diversion Control Division, on or before the date of its appearance. Truepill is not required to submit a corrective action plan, nor will any adverse inference be drawn if Truepill chooses not to do so. If Truepill wishes to submit a corrective action plan, it must be submitted directly to the Acting Assistant Administrator, Diversion Control Division, who will decide whether, in view of the plan and the allegations set forth in this Order to Show Cause, the proceedings to revoke Truepill's registration should be discontinued, or deferred for the purposes of modification, amendment, or clarification of such plan. Any corrective action plan should be clearly labeled "Corrective Action Plan" and submitted by email to Thomas W. Prevoznik, Acting Assistant Administrator, Diversion Control Division, at the following address: CAPresponse@usdoj.gov.

A copy of the corrective action plan shall also be served on Government counsel, Edward O. Siclari, and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, VA 22152.

In the event Truepill submits a corrective action plan and the Acting Assistant Administrator decides not to discontinue or postpone the proceedings, please note that such a decision is not a final determination by the agency regarding Truepill's corrective action plan or registration. In such circumstances, the Administrator may nonetheless consider the corrective action plan in issuing the final order at the conclusion of the proceedings.

Finally, please be advised that the submission of a corrective action plan shall not constitute a request for a hearing under paragraph 1 above or a written statement regarding Truepill's position on the matters of fact and law involved under paragraph 2 above. As indicated, if Truepill chooses to submit a corrective action plan and also wishes to proceed under paragraph 1 or 2 above, it must separately submit its request for a hearing (paragraph 1) or written statement (paragraph 2) in accordance with the instructions above.

THOMAS PREVOZNIK Digitally signed by THOMAS PREVOZNIK Date: 2022.12.15 17:15:08 -05'00'

Thomas W. Prevoznik
Acting Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Edward O. Siclari, Counsel for the Government

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
[redacted] Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

/s/ Brenda L. Head
Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): N/A

Physical Address: 2722 E Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Mohammad Middle: Umar Last: Afridi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Lavaca St PMB 40408

City: Austin State: TX Zip: 78701

Telephone: Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Manchester UK			06/2005	
Address		City	State	Zip
Oxford Rd		Manchester	UK	
Diploma/Degree obtained, if any				
Masters in Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22-Current	Sorrento, Hawley Lane	Hale Barns, WA15 ODR	UK	
12/21-7/22	[redacted] La Canada Way	Bee Cave	TX	78738
5/19-12/21	[redacted] Elisha Lane	San Ramon	CA	94583
1/18-5/19	[redacted] True Wind Way Unit 607	Redwood	CA	94063
1/16-1/18	[redacted] Willow Rd #202	Pleasanton	CA	94588
1/14-1/16	[redacted] W San Carlos St 383	San Jose	CA	95126
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Truepill			6/2016 - 8/2022	
Business Address		**City**	**State**	**Zip**
1700 S Amphlett Blvd		San Mateo	CA	94402
Phone	**Title**			
650-353-5495	CEO			

Description of Duties

Managed and directs the company toward goals and objectives, oversee executive business decisions

Business Name			From - To (MM/YY – MM/YY)	
CVS			12/2012 - 1/2016	
Business Address		**City**	**State**	**Zip**
Various Bay area locations		San Jose	CA	
Phone	**Title**			
	Pharmacist			

Description of Duties

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

Business Name			From - To (MM/YY – MM/YY)	
Rite Aid			9/2010-7/2012	
Business Address		**City**	**State**	**Zip**
		Seattle	WA	
Phone	**Title**			
	Pharmacist			

Description of Duties

Verified prescriptions for accuracy, patient consultations, supervise pharmacy technicians and clerks

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	✓	
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1/24/2019		CA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2017 80030	California Board of Pharmacy

Reason/Charge
Failure to provide documentation substantiating completion of continuing education. Unprofessional conduct

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

CI 2017 80030 issued on January 24, 2019
Mr. Afridi received a citation and fine following an audit of the Continuing Education ("CE") requirements imposed on pharmacists by the State of California. California Board of Pharmacy alleges Mr. Afridi had not completed all CE requirements to maintain his California Registered Pharmacist license.

Mr. Afridi has paid the fine imposed by the California Board of Pharmacy. Upon receipt of the fine, the California Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's California Registered Pharmacist License remains active in good standing.

Mr. Afridi has since registered for the NABP CE Monitor tracking service, enabling him to remain compliant now and in the future.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/16/2019		CA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CI 2019 86472	California Board of Pharmacy

Reason/Charge
furnished dangerous drugs on order of nurse practitioners who had not yet entered into an established protocol in place

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

CI 2019 86472 issued on December 16, 2019
Mr. Afridi received a citation while pharmacist-in-charge of Truepill PHY 56100. The California Board of Pharmacy alleges Truepill furnished dangerous drugs on order of nurse practitioners and physician assistants who had not yet entered into an established protocol in place.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/25/2021		AL		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-L-0080		Alabama Board of Pharmacy		
Reason/Charge				
Failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

21-L-0080 issued on October 25, 2021
Alabama Board of Pharmacy issued a Final Order to Mr. Mohammad Afridi, Alabama Registered Pharmacist #20384, regarding the California Board of Pharmacy Citation and Fine described below. Alabama Board of Pharmacy scheduled a reciprocal discipline hearing on the matter. The hearing was to discuss the California Board of Pharmacy Citation and Fine and to issue reciprocal discipline. Alabama Board of Pharmacy fined Mr. Afridi for failure to timely notify the Alabama Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Alabama Board of Pharmacy. Upon receipt of the fine, the Alabama Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Alabama Registered Pharmacist License remains active in good standing.

M. U. Afridi
Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/07/2022		MI		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
53-22-000152	Michigan Board of Pharmacy

Reason/Charge
Failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

53-22-000152 issued on 03/07/2022
Michigan Board of Pharmacy issued a consent Order to Mr. Mohammad Afridi, Michigan Registered Pharmacist #53-02-046254, regarding the California Board of Pharmacy Citation and Fine described below. Michigan Board of Pharmacy requested explanation of the California citation. Michigan Board of Pharmacy fined Mr. Afridi for failure to timely notify the Michigan Board of Pharmacy of the California Board of Pharmacy Citation and Fine. Mr. Afridi paid the fine to the Michigan Board of Pharmacy. Upon receipt of the fine, the Michigan Board of Pharmacy considered the matter closed and took no further action. Mr. Afridi's Michigan Registered Pharmacist License remains active in good standing.

Original Signature (electronic, copies or stamps not accepted)

6/12/23
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the Postmeds, Inc (direct owner of Seven Hills Pharmacy, LLC) has been involved in discipline cases. Which are described in Postmeds Discipline summary (provided along with the original NV application).

M.A

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 9 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Mohammed Afridi does not have a direct ownership interest in any licensed pharmacy. Mr. Afridi does have an ownership interest in the grandparent level holding company of licensed pharmacies. In the interests of transparency the following pharmacies (also owned by Postmeds Inc) were voluntarily closed:

Lake Forest Pharmacy, LLC - closed on 6/23/22
Belle Isle Pharmacy, LLC - closed on 6/23/22
Wind City pharmacy, LLC - closed on 6/14/22
Queen City Pharmacy, LLC - closed on 8/17/2022

The following pharmacies have also closed since the initial submission of this application:
Overlake Pharmacy, LLC - closed on 03/15/23
LA Pharmacy, LLC - closed on 03/15/23
Marymoor Pharmacy, LLC - closed on 04/21/23
River City Pharmacy, LLC - closed on 04/14/23

M.U.A

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mohammad Afridi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/12/23

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Siddharth Middle: Last: Viswanathan

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]ong Bridge Street, Apt 514

City: San Francisco State: CA Zip: 94158

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Carnegie Mellon University		09/2002-05/2006	
Address	**City**	**State**	**Zip**
5000 Forbes Avenue	Pittsburgh	PA	15213
Diploma/Degree obtained, if any			
Bachelor of Science Mechanical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Watkins Mill High School		09/1998-05/2002	
Address	**City**	**State**	**Zip**
10301 Apple Ridge Road	Gaithersburg	MD	20879
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2021 - Present	[redacted] Long Bridge Street, Apt 514	San Francisco	CA	94158
02/2017 - 12/2020	[redacted] Long bridge Street, Apt 705	San Francisco	CA	94158
09/2015 - 01/2017	[redacted] King Street, Apt 456	San Francisco	CA	94107
11/2009 - 08/2015	[redacted] Farrel Court	Mountain View	CA	94043
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Truepill			01/2016 - present	
Business Address		**City**	**State**	**Zip**
3100 Diablo Avenue		Hayward	CA	94545
Phone	**Title**			
855-910-8606	CEO and Co-Founder			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
LinkedIn			01/2011 - 08/2014	
Business Address		**City**	**State**	**Zip**
700 E. Middlefield Road		Mountain View	CA	94043
Phone	**Title**			
650-687-3600	Product Manager			
Description of Duties				

Worked on CardMunch and other relationship management products for the world's largest professional network. Led the integration, relaunch, and growth of LinkedIn CardMunch, which was the most downloaded iPhone application for busines

Business Name			From - To (MM/YY – MM/YY)	
Cardmunch, Inc. (acquired by LinkedIn)			11/2009 - 12/2010	
Business Address		**City**	**State**	**Zip**
57 W El Camino Rea		Mountain View	CA	94040
Phone	**Title**			
	Co-Founder			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Johnson & Johnson			07/2006 - 12/2008	
Business Address		**City**	**State**	**Zip**
One Johnson & Johnson Plaza		New Brusnwick	NJ	08933
Phone	**Title**			
732-524-0400	Global Operations Leadership Development			
Description of Duties				

Part of a 2-year rotational program and held positions in the medical device (orthopedic implants, diabetic monitors) and pharmaceutical sectors. Key project involved the ramp-up a new$70M distribution facility for the pharmaceutical business

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Siddharth Viswanathan

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/10/2022

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Francisco

I, Siddharth Viswanathan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/13/2022

Date

Subscribed and Sworn to before me this 13th day of October, 2022

Notary Public Signature

JUDY ANN PARDINI
Notary Public - California
San Mateo County
Commission # 2329943
My Comm. Expires Jul 23, 2024

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Mathew Middle: Sloan Last: Davis-Ratner

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] 51st Ave S

City: Seattle State: WA Zip: 98118

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Columbia Law School		2007-2010	
Address	**City**	**State**	**Zip**
435 W 116th St	New York	NY	10027
Diploma/Degree obtained, if any			
J.D			

School Name		From - To (MM/YY – MM/YY)	
Stanford University		2002-2007	
Address	**City**	**State**	**Zip**
450 Serra Mall	Stanford	CA	94305
Diploma/Degree obtained, if any			
M.A. and B.A.			

School Name		From - To (MM/YY – MM/YY)	
Troy High School		1998-2002	
Address	**City**	**State**	**Zip**
2200 Dorothy Ln	Fullerton	CA	92831
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2021 - present	[redacted]51st Ave S	Seattle	WA	98118
3/2020 - 12/2021	[redacted]Dahlia Pl	Corona del Mar	CA	92625
12/2018 - 2/2020	[redacted]44th Ave.	San Francisco	CA	94122
1/2017 - 12/2018	[redacted]Dahlia Pl	Corona del Mar	CA	92625
8/2015 - 12/2017	[redacted]Comerford Ln SE	Turner	OR	97392
5/2011 - 8/2015	[redacted]Dahlia Pl	Corona del Mar	CA	92625

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Truepill, Inc			3/2020-present
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
833-860-1057	General Counsel		
Description of Duties			
responsible for legal function of company			

Business Name			From - To (MM/YY – MM/YY)
Smith Health, Inc			4/2019-3/2020
Business Address	**City**	**State**	**Zip**
300 Brannan St	San Francisco	CA	94107
Phone	**Title**		
8444540123	Head of Legal and Corporate Operations		
Description of Duties			
responsible for legal, compliance, people and facilities functions of company			

Business Name			From - To (MM/YY – MM/YY)
Incipio, LLC			1/2017-8/2018
Business Address	**City**	**State**	**Zip**
3347 Michelson Dr STE 100	Irvine	CA	92612
Phone	**Title**		
8007330088	General Counsel & Secretary		
Description of Duties			
responsible for legal function of company			

Business Name			From - To (MM/YY – MM/YY)
Kundalini Farms, LLC			8/2015-12/2019
Business Address	**City**	**State**	**Zip**
14415 Comerford Ln SE	Turner	OR	97392
Phone	**Title**		
n/a	Co-Founder		
Description of Duties			
esponsible for operational functions of company			

Business Name			From - To (MM/YY – MM/YY)
Nextgen Healthcare, Inc			7/2013-9/2015
Business Address	**City**	**State**	**Zip**
18111 Von Karman Ave Suite 600	Irvine	CA	92612
Phone	**Title**		
9492552600	Vice President, Associate General Counsel and Assistant Secretary		
Description of Duties			
member of legal function of company			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Latham & Watkins LLP			11/2010-7/2013	
Business Address		**City**	**State**	**Zip**
650 Town Center Dr #20		Costa Mesa	CA	92626
Phone	**Title**			
7145401235	Associate			
Description of Duties				
associate in legal services organization				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mathew Davis-Ratner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

Please have this section completed in the presence of a Notary Public.

State of Washington, ss. County of King

I, Mathew Davis-Ratner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/28/22

Date

Subscribed and Sworn to before me this 28 day of October 2022.

Notary Public Signature

GENNELL CLAUDETTE HUNTER
Notary Public
State of Washington
Commission # 203817
My Comm. Expires Oct 11, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/Wholesaler License # (if applicable): 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website:

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Christopher Middle: William Last: Spitzer

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Gardenside Lane

City: Loveland State: OH Zip: 45140

Telephone: Email: christopher.spitzer@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Massachusetts, Dartmouth		09/16 - 05/18	
Address	**City**	**State**	**Zip**
285 Old Westport Rd	North Dartmouth	MA	02747
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Sciences		09/04 - 05/10	
Address	**City**	**State**	**Zip**
179 Longwood Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Gateway Regional High School		09/00 - 06/04	
Address	**City**	**State**	**Zip**
12 Littleville Rd	Huntington	MA	01050
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18 - present	[redacted] Gardenside Ln	Loveland	OH	45140
10/17 - 03/18	[redacted] Sanctuary Ln	Maineville	OH	45039
09/13 - 09/17	[redacted] Winchester St	Brookline	MA	02446
09/10 - 08/13	[redacted] Island Hill Ave	Malden	MA	02148
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Seven Hills Pharmacy				From - To (MM/YY – MM/YY): 09/21 - present
Business Address: 2722 E. Kemper Rd		City: Sharonville	State: OH	Zip: 45241
Phone: (513) 771-0367	Title: Pharmacist-in-Charge			Number of Employed Hours: 2,200
Description of Duties: Managing all pharmacy operations, hiring pharmacy/warehouse personnel, filling/shipping prescriptions, inventory management				

Business Name: CVS Health				From - To (MM/YY – MM/YY): 1/18 - 8/21
Business Address: 13 Mary St		City: Cincinnati	State: OH	Zip: 45216
Phone: (800) 746-7287	Title: District Leader, Pharmacy Supervisor, Pharmacy Manager			Number of Employed Hours: 7,040
Description of Duties: Responsible for the overall retail store operations in assigned district (28 Stores), P&L management, operating COVID clinics, inventory management				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Spitzer Pharmacist Registration #: 03236754

Pharmacy Name: Seven Hills Pharmacy, LLC

Initial each statement below to indicate you have read and agree with the following:

CS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Written Reprimand and Penalty	Ohio	3/9/2022	A-2021-0336

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A					

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted) Date 12/7/22

Christopher W. Spitzer
[redacted] Gardenside Ln
Loveland, OH 45140
[redacted]

September 9, 2022

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

To whom it may concern,

Attached please find the details concerning a recent settlement between myself and the Ohio Board of Pharmacy. The fine of $250 has already been paid and the additional CE hours (5) will be submitted by the end of the month.

If you need any more information from me feel free to reach out via phone/email at any time.

Sincerely,

Christopher W. Spitzer

RECEIVED
SEP 19 2022
NEVADA STATE BOARD
OF PHARMACY

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2021-0336

Christopher Spitzer, RPh
[redacted] Gardenside Lane
Loveland, Ohio 45140

License No. 03-236754

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Christopher Spitzer, RPh, for the purpose of resolving all issues between the parties relating to the Board investigation of Christopher Spitzer and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol. Together, the Board and Christopher Spitzer are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.16 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.07 and 4729.08 of the Ohio Revised Code to practice pharmacy in the state of Ohio.

2. Christopher Spitzer is a licensed pharmacist in the state of Ohio under license number 03-236754, who was listed as the District Manager at CVS Pharmacy #6123, located at 7500 Beechmont Avenue, Cincinnati, Ohio, at the time of the Allegations in the Notice of Opportunity for Hearing dated March 9, 2022.

FACTS

1. The Board initiated an investigation of Christopher Spitzer, pharmacist license number 03-236754, and CVS Pharmacy #6123 for failing to report a pharmacist for arriving to work his scheduled shift at CVS Pharmacy while impaired and under the influence of alcohol.

2. On or about March 9, 2022, the Board sent a Notice of Opportunity for Hearing to Christopher Spitzer, which outlined the allegations and provided notice of his right to a hearing, his rights in such hearing, and his right to submit contentions in writing.

3. On or about March 31, 2022, Christopher Spitzer, timely requested an administrative hearing, which was subsequently scheduled for April 6, 2022. Settlement of this matter was reached prior to hearing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Christopher Spitzer neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated March 9, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Christopher Spitzer agrees to pay to the Board a monetary penalty in the amount of $250.00. This fine will be attached to Christopher Spitzer' license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

4. Christopher Spitzer must obtain five hours of approved continuing pharmacy education (0.5 CEUs) which may not also be used for license renewal. The 0.5 CEUs must be completed within six months from the effective date of this agreement. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

5. The Board hereby imposes a written reprimand on Christopher Spitzer's pharmacist license, number 03-236754.

6. Christopher Spitzer agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Christopher Spitzer understands that he has the right to be represented by counsel for review and execution of this agreement.

8. Christopher Spitzer agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which he currently holds a professional license, including to the Board on renewal applications or applications for a new license.

9. Christopher Spitzer explicitly withdraws his request for a hearing, waives an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

14. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Christopher Spitzer, RPh, Respondent	7/20/22 Date of Signature
James F. Leo, Attorney for Respondent	7/20/22 Date of Signature
Shawn Wilt, RPh, President, State of Ohio Board of Pharmacy	08.11.2022 Date of Signature
N/A Henry Appel, Ohio Assistant Attorney General	N/A Date of Signature

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Spitzer, **certify that as the designated representative for**

Seven Hills Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Spitzer
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Spitzer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/18/22

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Hamilton

I, Christopher Spitzer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/18/22

Date

Subscribed and Sworn to before me this 18th day of October 2022

Notary Public Signature

HAYLEY ABNEY - NOTARY PUBLIC
COMM EXP: AUG 4 2025
STATE OF OHIO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable): OH 0232000312

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: N/A

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Daniel Middle: Yitzhak Last: Simkin

Alias(es, nicknames, name changes, etc.): Donny Simkin

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted] Hyperion Ave

City: Los Angeles State: CA Zip: 90029

Telephone: [redacted] Email: compliance@truepill.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Valley Torah High School		09/96 - 06/00	
Address	City	State	Zip
12517 Chandler Blvd	Valley Village	CA	901607
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Stanford University		09/03 - 06/07	
Address	City	State	Zip
450 Serra Mall	Stanford	CA	94305
Diploma/Degree obtained, if any			
BA English			

School Name		From - To (MM/YY – MM/YY)	
UCLA School of Law		08/13 - 05/16	
Address	City	State	Zip
385 Charles E Young Dr E	Los Angeles	CA	90095
Diploma/Degree obtained, if any			
JD			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 - Present	[redacted]Hyperion Ave	Los Angeles	CA	90029
05/15 - 07/19	[redacted]Lucile Ave #1	Los Angeles	CA	90027
02/15 - 05/15	[redacted]S Wooster St #1	Los Angeles	CA	90035
04/14 - 02/15	[redacted]Weyburn Ter # 216	Los Angeles	CA	90024
10/12 - 04/14	[redacted]Castle Heights Ave	Los Angeles	CA	90034
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Truepill, Inc.			From - To (MM/YY – MM/YY): 08/21 - Present	
Business Address: 3121 Diablo Ave		City: Hayward	State: CA	Zip: 94545
Phone: (855) 910-8606	Title: Associate General Counsel			
Description of Duties: Attorney				

Business Name: Barta Tate			From - To (MM/YY – MM/YY): 04/18 - 03/20	
Business Address: 1801 Century Park E STE 1200		City: Los Angeles	State: CA 9006	Zip:
Phone: (310) 479 - 1454	Title: Associate			
Description of Duties: Attorney				

Business Name: Strook & Stroock & Lavan LLP			From - To (MM/YY – MM/YY): 09/16 - 12/17	
Business Address: 2029 Century Park E 18th Floor		City: Los Angeles	State: CA	Zip: 90067
Phone: (310) 556 - 5800	Title: Associate			
Description of Duties: Attorney				

Business Name: Sparks Consulting			From - To (MM/YY – MM/YY): 08/12 - 09/13	
Business Address: Virtual		City:	State:	Zip:
Phone: (214) 557 - 0111	Title: Senior Associate			
Description of Duties: Athletic and academic counseling				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✔	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/25/2012	N/A	CA	Los Angeles	Los Angeles
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
#3VY002301-01		Superior Court of California		
Reason/Charge				
Driving under the influence of an alcoholic beverage				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
DANIEL YITZHAK SIMKIN			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

On January 29, 2013, Manager Daniel Simkin received a misdemeanor alcohol DUI conviction under California Vehicle Code section 23152(b). See Los Angeles Superior Court (2013), Case #3VY002301-01; see also Exhibit A, Misdemeanor Sentencing Memorandum – Vehicle Code. On March 22, 2016, this misdemeanor conviction was dismissed under California Penal Code section 1203.4. See Exhibit B, Order for Dismissal.
On January 11, 2018, Mr. Simkin was admitted to the State Bar of California and remains active and in good standing (State Bar Number: 319806).

Original Signature (electronic, copies or stamps not accepted)

10/28/22
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Simkin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/28/22

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Daniel Simkin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/31/22

Date

Subscribed and Sworn to before me this 31st day of October 2022.

Notary Public Signature

KEITH McGRUDER
COMM# 2293123
Notary Public - California
Los Angeles County
My comm. Expires July 12, 2023

(Seal)

Exhibit A

SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA,
OR 01/15/2013 Bkg no. 3409911
Plaintiff,

vs.

DANIEL YITZHAK SIMKIN [redacted] M

V23152a/no prior

V23152b

Defendant(s).

MISDEMEANOR COMPLAINT

Case number: 3VY00230

FILED
JOHN A. CLARKE
Executive Officer/Clerk

By_____
Deputy Clerk

Issued by
CARMEN A. TRUTANICH
City Attorney

By_____
KATHLEEN FORD (LT)
Deputy City Attorney

Comes now the undersigned and states that he is informed and believes, and upon such information and belief declares: That on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (a) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle while being under the influence of an alcoholic beverage and a drug and under the combined influence of an alcoholic beverage and a drug.

MCI 23152(A)/29

COUNT II

For a further, separate and second cause of action being a different offense, belonging to the same class of crimes and offenses set forth in Count I hereof, affiant further alleges that on or about 12/25/2012 at and in the City of Los Angeles, in the County of Los Angeles, State of California, a misdemeanor, to wit, violation of Subdivision (b) of Section 23152 of the California Vehicle Code was committed by the above-named defendant(s) (whose true name(s) to affiant is(are) unknown), who at the time and place last aforesaid, did willfully and unlawfully drive a vehicle with 0.08 percent or more, by weight, of alcohol in his or her blood.

The allegations of prior convictions listed in Count I of this complaint are hereby incorporated by reference as allegations of prior convictions for the purposes of this Count of the complaint.

MCI 23152(B)/29

All of which is contrary to the law and against the peace and dignity of the People of the State of California. Declarant and complainant therefore prays that a warrant may be issued for the arrest of said defendant(s) and that he may be dealt with according to law.

Attached hereto and incorporated by reference as though fully set forth are written statements and reports which constitute the basis upon which I make the within allegations.

A declaration in Support of the Issuance of Such Warrant is Submitted.

Executed at Los Angeles, California, on

I declare under penalty of perjury that the foregoing is true and correct.

A. Martinez
Declarant and Complainant

INFORMAL DISCOVERY NOTICE

TO THE ABOVE-NAMED DEFENDANT(S) AND/OR ATTORNEY(S) FOR DEFENDANT(S):

Plaintiff, the People of the State of California, hereby requests discovery/disclosure from the defendant(s) and his or her attorney(s) in this case pursuant to Penal Code Sections 1054.3 and 1054.5.

YOU ARE HEREBY NOTIFIED that if complete disclosure is not made within 15 days of this request, plaintiff will seek -- on or before the next court date, or as soon as practicable thereafter -- a court order enforcing the provisions of Penal Code Section 1054.1, subdivisions (b) and (c). This is an ongoing request for any of the listed items which become known to the defendant(s) and his or her attorney(s) after the date of compliance.

The written statements and reports attached hereto constitute discoverable materials designated in Penal Code Section 1054.1. Any additional material discoverable pursuant to Penal Code Section 1054.1 that becomes known to plaintiff will be provided to the defense.

If, prior to or during trial, as a result of this request plaintiff obtains additional evidence or material subject to disclosure under a previous defense request or court order pursuant to Penal Code Section 1054.1, plaintiff will disclose the existence of that evidence or material within a reasonable time.

DISCOVERY MATERIALS SHOULD BE DELIVERED TO A DEPUTY CITY ATTORNEY IN TRIAL COURT ON THE FIRST TRIAL DATE.

Line Reference Target LRT-BE4-V3

SUPERIOR COURT OF CALIFORNIA, COUNTY OF LOS ANGELES

MISDEMEANOR SENTENCING MEMORANDUM - VEHICLE CODE

Defendant: DANIEL Simko			Case No: 3VY00110
Date:	Dept/Div: 103	Prosecutor:	Defense: Simon Mahavi
Judge: OMAN S	Clerk: H. ARROX	Reporter:	Interpreter/Language:

As to Count 1, a violation of Penal Code § [ ] 23152(a) [ ] 23152(b) [ ] 23103 per 23103.5 [ ] 14601 __ [ ] 12500(a) [ ] _____ with ___ admitted priors.

Arraignment For Judgment

[ ] Arraignment for judgment and time for sentencing waived. There is no legal cause why judgment should not now be pronounced.

Sentence

1. [ ] **Probation is denied.** Defendant is to serve ____ days/hours in the Los Angeles County Jail, forthwith. [ ] consecutive [ ] concurrent with _____
   Defendant to receive total credit of _____ days/hours (credit _____ days/hours actual plus _____ days GT/WT).
2. [ ] Pay a fine of $ _____ plus all applicable penalty assessments and enhancements.
3. [ ] Pay all fines and assessments as set forth in Paragraph 20 below.
4. [ ] **Execution of the foregoing sentence is suspended, on the following terms and conditions.**

Conditional Sentence (PC §1203b/Order of Probation (PC §1203a)

[ ] **Imposition of sentence is suspended (ISS)** [ ] With supervision by county probation officer (formal probation)
For a period of 36 months upon the following terms and conditions:

1. [ ] **Serve _____ days/hours in the Los Angeles County jail,** [ ] consecutive [ ] concurrent with _____
   Defendant to receive credit of _____ days/hours actual plus _____ days/hours GT/WT. [ ] Time may be served in any penal institution
   [ ] Time may be served on consecutive weekends of two days each, beginning _____ **(772)**
   [ ] Time may be served in any city jail having actual confinement, at defendant's expense. **(021)**
   [ ] Defendant may not participate in Sheriff's home detention/EHM per PC 1203.016(e). **(771)** [ ] Work furlough / early release not allowed
   [ ] Last _____ days of jail time to be served in: [ ] Antelope Valley Rehabilitation Center [ ] _____ Program. **(002)**
   Defendant to be released only to an authorized representative of that program and is to comply with all program terms and conditions. **(013)**
   If defendant leaves or is discharged from the program prior to completion, defendant is to report to court on the next court day. **(013)**
2. [ ] **Pay a fine of $ 390 plus penalty assessments or** in default thereof serve ____ additional days in County jail consecutive **or** perform _____ days of Community Labor/ _____ or perform ____ days/hours of approved Community Service with credit for _____ days actual or $_____ toward fine for jail time already served. [ ] Fine may be paid in monthly installments of $_____ **(124)** [ ] Defendant to report to Financial Evaluator to work out a payment plan.
   [ ] Defendant elects jail in lieu of fine, forthwith, consecutive to all other time, credit _____ days actual plus _____ days GT/WT.
3. [ ] Perform _____ days of work for Community Labor/ _____ or perform _____ days/hours of approved Community Service, with credit for _____days actual. Sign up for all work or Community Service only at a court-approved volunteer center or in the clerk's office.
   Failure to complete court-ordered work or Community Service without excuse may result in jail. **This work or Community Service is in addition to that done in lieu of fine.**
4. [ ] Make **restitution to victim** _____ per PC §1202.4(f) **(048)** [ ] in an amount to be determined at a hearing. **(067)** [ ] *Harvey* waiver taken.
   [ ] in the stipulated sum of $_____ **(048)** [ ] per any final civil judgment against you. **(100)** [ ] Liability is admitted but amount is disputed.
5. [ ] **Enroll within 21 days (or within 21 days from your release from custody) and successfully complete an approved:** Defendant's BAC: ___.__ %. [ ] **Refusal**
   [ ] 12 hour (SB 1176) [ ] 3 mo. (AB541)**(327)** [ ] 6 mo. (AB 768) [ ] 9 mo. (AB1353) [ ] 18 mo. (SB38)**(328)** [ ] 30 mo. alcohol education program.
   The DMV will not restore your driving privilege until you successfully complete a licensed alcohol education program. [ ] Obtain program details Clerk or Health Officer.
6. [ ] Attend 16 Alcoholics Anonymous/Narcotics Anonymous meetings at the rate of 2 times per week, IN ADDITION to those required as part of the alcohol education program. **(246)** one per day
7. [ ] **Do not drive any vehicle with any measurable amount of alcohol or drugs in your blood,** or refuse to take and complete any blood alcohol/drug chemical test, any field sobriety test or any preliminary alcohol screening test when requested by any peace officer. **(711)**
8. [ ] Do not drive a motor vehicle without a valid driver's license in your possession, or without liability insurance in at least the minimum amounts required b law. **(374)**
9. [ ] Abstain from the use of all alcoholic beverages and stay out of all places where they are a chief item of sale. **(300)**
10. [ ] Enroll in and complete the [ ] Hospital and Morgue ("HAM") Program. **(471)** [ ] MADD Victim Impact Program **(472)** [ ] _____
11. [ ] The court finds that defendant presents a traffic safety or public safety risk and, per VC §13352.4(d), disallows issuance by DMV of a restricted license. **(249)**
12. [ ] **Your driver's license is hereby ordered [ ] suspended [ ] revoked** for a period of ____ months ____ years. [ ] **"M" service given in open court. (283)**
    You may not drive a motor vehicle unless and until your driving privilege is restored. [ ] Defendant under age 21 at time of offense.
13. [ ] You are hereby declared to be a Habitual Traffic Offender for a period of _____ years. **(263)**
14. [ ] Comply with the "Supplemental Terms of Probation – Ignition Interlock Device" regarding installation of an ignition interlock. **(248)** DMV
15. [ ] Do not own, use possess, buy or sell any controlled substances, or associated paraphernalia, except with valid prescription, and stay away from places where users, buyers or sellers congregate. Do not associate with persons known by you to be controlled substance users or sellers, except in an authorized drug counseling program. **(926)**
16. [ ] Submit your person and property to search and seizure at any time of the day or night, by any Probation Officer or other peace officer, with or without a warrant, probable cause or reasonable suspicion. **(576)**
17. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered impounded for _____ days per Vehicle Code § 23594(a). **(703)**
18. [ ] The vehicle with license plate _____ is, after notice and hearing, ordered confiscated and sold per Vehicle Code § 23596(a).
19. [ ] If you are deported from or otherwise leave the United States, notify the Court [and Probation] in writing of your address and telephone number outside the United States within 72 hours of deportation or departure. Continue to pay all of your financial obligations to the Court [and to Probation] while outside the United States. **(474)**
20. [ ] **Pay all of the following (check all that apply):**

[ ] **A restitution fine** of [ ] $100.00, [ ] $_____ per PC §1202.4(b) through (e). **(098)**	[ ] **An administrative screening fee** of $25 per PC 1463.07/GC §29550(f) (D released OR.)
[ ] **A probation revocation restitution fine** in the same amount as the restitution fine, per PC §1202.44, payment is stayed until probation is revoked and sentence imposed.	[ ] **A citation processing fee** of $10.00 per PC §1463.07 and GC §29550(f) (if D cited and released in field or at jail facility.)
[ ] **A criminal conviction/facilities assessment** of $30.00 per Gov't Code §70373(a). (SA:CC)	[ ] An alcohol abuse education and prevention penalty assessment of $_____ ($50 max.) per VC §23645.
[ ] **A criminal fine surcharge** of $_____ per Penal Code §1465.7 (20% of base fine). (SA:AB)	[ ] An alcohol and drug problem program assessment of $_____ ($100.00 max.) per VC §23649.
[ ] **A court security fee** of $20.00 per PC §1465.8(a)(1). (per count) (SA:SF)	[ ] A drug program fee of $150.00 (per drug count except §11357(b)) per H&S §11372.7(a).
[ ] **A criminal justice administration fee** of $_____ payable to the local arresting agency, per Gov't Code §§ 29550(c), 29550.1 or 29550.2 (agency's actual cost)	[ ] A crime lab fee of $50.00 plus penalty assessment per H&S Code §11372.5. **(184)**
[ ] **Cost of probation services** per PC 1203.1b, [ ] as determined by the Probation Officer, subject to a hearing if requested, [ ] in the amount of $_____ per month.	[ ]

21. [ ] NOTIFY DMV OF ANY ADDRESS CHANGE WITHIN 10 DAYS
22. [ ] **Obey all laws** and orders of the Court (541), [ ] and rules and regulations of the Probation Department. **(542)**
    [ ] **Defendant acknowledges that he/she understands and accepts the terms and conditions of probation. (810)**
    [ ] Defendant ordered to pay attorney fees [ ] in the amount of $_____ [ ] in the amount determined by the Financial Evaluator.
    [ ] **Counts/allegations** _____ **are dismissed/stricken** on the People's motion pursuant to Penal Code Section 1385 as to this defendant.

Compliance Dates: Defendant is ordered to appear in person on each of the following compliance dates. (683)

Surrender for jail: [ ] *Cruz* waiver taken:		Restitution Hearing in Div/Dep't _____ at 8:30 a.m.	
Pay fine/fees in full by: [ ] installments allowed	1-29-14 c/o	POE/Proof of Completion of Alcohol Program:	6-28-13 c/o
Complete jail/work/c-s by:		Other:	

I understand, accept and will comply with the foregoing conditional sentence and compliance dates and will return to Court as ordered.

Defendant's Signature:	Attorney's Signature Joining:

Defendant's Address: _____
Defendant's Telephone: _____

_____
Judge/Commissioner of the Superior Court

CRIM 088 (Rev. 5/1/09) DISTRIBUTION: Pink - Court Copy White - Defendant Copy

Exhibit B

CR-181

ATTORNEY OR PARTY WITHOUT ATTORNEY:	STATE BAR NO.:	FOR COURT USE ONLY
NAME: Daniel Yitzhak Simkin		FILED
FIRM NAME:		LOS ANGELES SUPERIOR COURT
STREET ADDRESS: [redacted]Lucile Avenue APT 1		MAR 23 2016
CITY: Los Angeles	STATE: CA ZIP CODE: 90026	Sherri R. Carter, Executive Officer/... Dep.
TELEPHONE NO.: [redacted]	FAX NO.:	By Bonnie Leck
E-MAIL ADDRESS: [redacted]		
ATTORNEY FOR (name):		

PEOPLE OF THE STATE OF CALIFORNIA
v.
DEFENDANT: Daniel Yitzhak Simkin DATE OF BIRTH: [redacted]

ORDER FOR DISMISSAL
(Pen. Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, 1203.49)

CASE NUMBER: 3VY00230-01

The court finds from the records on file in this case, and from the foregoing petition, that the petitioner *(the defendant in the above-entitled criminal action)* is eligible for the following requested relief:

1. The court **GRANTS** the petition for reduction of a felony to a misdemeanor (maximum punishment of 364 days per Pen. Code, § 18.5) under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) and reduces the following convictions:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

2. The court **DENIES** the petition for reduction of a felony to a misdemeanor under Penal Code section 17(b) and/or for reduction of a misdemeanor to an infraction under Penal Code section 17(d)(2) for:
   - ☐ ALL FELONY CONVICTIONS in the above-entitled action;
   - ☐ ALL MISDEMEANOR CONVICTIONS in the above-entitled action; OR
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

3. The court **GRANTS** the petition for dismissal regarding the following convictions under Penal Code ☒ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49, and it is ordered that the pleas, verdicts, or findings of guilt be set aside and vacated and a plea of not guilty be entered and that the complaint be, and is hereby, dismissed for:
   - ☒ ALL CONVICTIONS in the above-entitled action, or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

4. The court **DENIES** the petition for dismissal regarding the following convictions under Penal Code ☐ § 1203.4, or ☐ § 1203.4a, or ☐ § 1203.41, or ☐ § 1203.49 for:
   - ☐ ALL CONVICTIONS in the above-entitled action; or
   - ☐ Only the following convictions in the above-entitled action *(specify charges and date of conviction)*:

5. In granting this order under the provisions of Penal Code section 1203.49:
   a. The court finds that the petitioner was a victim of human trafficking when he or she committed the crime.
   b. ☐ The court orders the relief described in section 1203.4, or
      ☐ The court orders the relief described in section 1203.4, with the following exceptions *(specify)*:

Form Approved for Optional Use
Judicial Council of California
CR-181 [Rev. January 1, 2016]

ORDER FOR DISMISSAL

Penal Code, §§ 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, and 1203.49
www.courts.ca.gov

CR-181

PEOPLE OF THE STATE OF CALIFORNIA v DEFENDANT:	CASE NUMBER:
DANIEL YITZHAK Simkin	3VY00230-01

6. If this order is granted under the provisions of Penal Code section 1203.4 or 1203.41:
   a. The petitioner is required to disclose the above conviction in response to any direct question contained in any questionnaire or application for public office, or for licensure by any state or local agency, or for contracting with the California State Lottery Commission.
   b. Dismissal of the conviction does not *automatically* relieve petitioner from the requirement to register as a sex offender. (See, e.g., Pen. Code, § 290.5.)

7. If the order is granted under the provisions of Penal Code section 1203.49, the Department of Justice is hereby notified that the petitioner was a victim of human trafficking when he or she committed the crime, and the relief ordered.

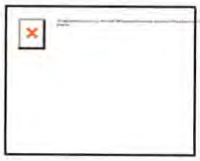
8. If the order is granted under the provisions of either Penal Code section 1203.4, 1203.4a, 1203.41, or 1203.49, the petitioner is released from all penalties and disabilities resulting from the offense except as provided in Penal Code sections 29800 and 29900 (formerly sections 12021 and 12021.1) and Vehicle Code section 13555. In any subsequent prosecution of the petitioner for any other offense, the prior conviction may be pleaded and proved and shall have the same effect as if probation had not been granted or the accusation or information dismissed. The dismissal does not permit a person to own, possess, or have in his or her control a firearm if prevented by Penal Code sections 29800 or 29900 (formerly sections 12021 and 12021.1). Dismissal of a conviction does not permit a person prohibited from holding public office as a result of that conviction to hold public office.

9. In addition, as required by Penal Code section 299(f), relief under Penal Code sections 17(b), 17(d)(2), 1203.4, 1203.4a, 1203.41, or 1203.49 does *not* release petitioner from the separate administrative duty to provide specimens, samples, or print impressions under the DNA and Forensic Identification Database and Data Bank Act (Pen. Code, § 295 et seq.) if petitioner was found guilty by a trier of fact, not guilty by reason of insanity, or pled no contest to a qualifying offense as defined in Penal Code section 296(a).

Date: 3/22/16

Rebecca Dixon

(JUDICIAL OFFICER)



Loan Nguyen, PharmD
Senior Manager, Pharmacy Compliance

m. 408.393.7292
e. loan.nguyen@truepill.com
w. www.truepill.com

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Can you please provide it? We can attach it to your application and work to process this request.

Regards,

Olivia Mora

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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--

Thank you,

Artiom Solovei
Compliance Generalist

m. 727.836.0418
e. artiom.solovei@truepill.com
w. www.truepill.com

On Thu, Jan 19, 2023 at 3:12 PM Loan Nguyen <loan.nguyen@truepill.com> wrote:

Art, please work on deficiency items. This was in my spam inbox.

---------- Forwarded message ---------
From: **Olivia Mora** <o.mora@pharmacy.nv.gov>
Date: Wed, Jan 18, 2023 at 8:45 AM
Subject: Out of State Pharmacy - Seven Hills Pharmacy, LLC - Sharonville, OH - Need more information
To: compliance@truepill.com <compliance@truepill.com>

To whom it may concern:

We received the Pharmacy Application for Seven Hills Pharmacy, LLC. Please be advised that we are missing the below documentation -

- Certificate of Good Standing or Certificate of Corporate Status from the Secretary of State where the business is domiciled. (Certificate needs to be dated within 1 yr)
- Copy of Most Recent Inspection
- Home State License
- List of Officers and Directors
- Copy of DEA (if applicable)
- Page 3 of the Pharmacy application - Yes to question 3 – need signed statement of Explanation and copies of any documents that identify the circumstance or contain an order, agreement, or other disposition.
- Designated Representative application - need a signed statement of Explanation and copies of any documents that identify the circumstances or contain an order, agreement, or other disposition.
- Personal History application (Daniel Simkin) – need copies of any documents that identify the circumstances or contain an order, agreement, or other disposition.
- Credit Card information is invalid unable to process payment.

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From: Artiom Solovei <artiom.solovei@truepill.com>
Sent: Friday, January 20, 2023 7:49 AM
To: Olivia Mora <o.mora@pharmacy.nv.gov>; Compliance Compliance <compliance@truepill.com>
Subject: Re: Out of State Pharmacy - Seven Hills Pharmacy, LLC - Sharonville, OH - Need more information

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good Morning Olivia,

Thank you for your email.

Per your request we have prepared all deficiency items. You can find them attached below:

- Certificate of Good Standing or Certificate of Corporate Status from the Secretary of State where the business is domiciled. -new cert dated 11/07/2022
- Copy of Most Recent Inspection - inspection dated 11/07/2022
- Home State License - attached
- List of Officers and Directors - list of managers attached since it is LLC
- Copy of DEA (if applicable) - attached
- Page 3 of the Pharmacy application - Yes to question 3 – need signed statement of Explanation and copies of any documents that identify the circumstance or contain an order, agreement, or other disposition. - LOE attached with supporting docs
- Designated Representative application - need a signed statement of Explanation and copies of any documents that identify the circumstances or contain an order, agreement, or other disposition. - attached
- Personal History application (Daniel Simkin) – need copies of any documents that identify the circumstances or contain an order, agreement, or other disposition. - supporting documents attached
- Credit Card information is invalid unable to process payment. - form corrected (can we get a receipt)

If any additional info is needed please let me know.

From: Olivia Mora
Sent: Wednesday, January 25, 2023 9:58 AM
To: Artiom Solovei <artiom.solovei@truepill.com>; Compliance Compliance <compliance@truepill.com>
Subject: RE: Out of State Pharmacy - Seven Hills Pharmacy, LLC - Sharonville, OH - Need more information

Hi Artiom,

Thank you for providing the documentation.

However, I was unable to find the attached documents for the following.

- Personal History application (Daniel Simkin) – need copies of any documents that identify the circumstances or contain an order, agreement, or other disposition. - supporting documents attached
- Also, if you can update page 6 and 7 of the Designated Rep application due to there is a Yes answer on Section 11 of the Pharmacy Application.

Can you please provide?

Thank you,

Olivia Mora

Licensing Specialist

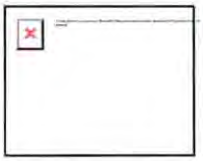
Nevada State Board of Pharmacy

(775) 850-1440

o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

Thank you,



Artiom Solovei
Compliance Generalist

m. 727.836.0418
e. artiom.solovei@truepill.com
w. www.truepill.com

On Wed, Jan 25, 2023 at 12:59 PM Olivia Mora <o.mora@pharmacy.nv.gov> wrote:

If you can please email me both request of information.

Regards,

Olivia Mora

Licensing Specialist

Nevada State Board of Pharmacy

(775) 850-1440

o.mora@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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Olivia Mora

From: Artiom Solovei <artiom.solovei@truepill.com>
Sent: Friday, February 17, 2023 8:24 AM
To: Olivia Mora
Cc: Compliance Compliance
Subject: Re: Out of State Pharmacy - Seven Hills Pharmacy, LLC - Sharonville, OH - Need more information
Attachments: 2022.10.13 Personal History Application - SIMKIN(signed)1.pdf; Truepill - Response to OTSC.pdf; Truepill - OTSC_12.15.2022.pdf; 2023.02.06 - Postmeds, Inc. - BOP Summary.docx.pdf; Postmeds, Inc dba Truepill_Kansas amended Summary order.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good Morning Olivia,

Thank you for your patience.

Deficiency items:
1) Personal History application (Daniel Simkin) – need copies of any documents that identify the circumstances or contain an order, agreement, or other disposition. - The Personal History application is attached and the supporting documents are included in the document.

2) Designated Representative app pages 6 & 7 - none of these questions describe the PIC's reprimand. We can't put a "yes" on any of the questions.
The PIC's disciplinary reprimand falls under Section 11 of the Pharmacy Application but not to any questions from Designated Representative app pages 6 & 7

3) We would like to update our application to disclose recent action on the pharmacy's owner, Postmeds. Inc. Please see attached.
Thank you,

Thank you,

Artiom Solovei
Compliance Generalist

m. 727.836.0418
e. artiom.solovei@truepill.com
w. www.truepill.com

On Wed, Jan 25, 2023 at 3:19 PM Artiom Solovei <artiom.solovei@truepill.com> wrote:
Hello Olivia,

Thank you for letting us know.
I will work on the requested deficiency items.

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☒ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 01886	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FW0066856 ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Women's International Pharmacy, Inc.

Physical Address: 12012 N. 111th Ave

City: Youngtown State: AZ Zip: 85363

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 800-699-8143 Toll Free # (NAC 639.708, NRS 639.23286): 800-699-8143

Fax: 800-330-0268 Contact Email: michelle.violi@belmarpharma.com

Website: www.womensinternational.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Elmer Mares Morales

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22926

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Elmer Mares Morales	NV Pharmacist Registration #: 22926
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Wisconsin

Parent Company (if any): Belmar Midco, Inc.

Corporation/Organization Name: Women's International Pharmacy, Inc.

Mailing Address: 2 Marsh Ct.

City: Madison State: WI Zip: 53718

Telephone: 608-221-7800 ext. 1113 Email: michelle.violi@belmarpharma.com

Contact Person Name: Michelle Violi

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO and President (title) for Women's International Pharmacy, Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Robert J Kilgore

Print Name of Authorized Person

Robert J Kilgore

Original signature of Authorized Person (copies or stamps not accepted)

11-20-2023

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert J. Kilgore

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Robert J Kilgore — 11-20-2023

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 11/22/23	Amount: $500 - check 27238

To clarify, the applicant, Women's International Pharmacy, Inc. located in **Youngtown, Arizona**, has no disciplinary history to report.

However, Women's International Pharmacy, Inc. also operates a pharmacy in Madison, Wisconsin and, out of an abundance of caution, we disclose the following information in response to Section 3: question 3 on the Pharmacy application submitted to add sterile compounding permissions to existing Nevada permit number PH01886 for Women's International Pharmacy, Inc. in Youngtown, AZ.

In 1995, Women's International Pharmacy, Inc. of **Madison, Wisconsin** ("Women 's-Wisconsin") entered into the attached Stipulation to resolve a disciplinary proceeding before the Wisconsin Pharmacy Examining Board. The Stipulation imposed certain limitations on Women's-Wisconsin's resident pharmacy license, however, those limitations were removed nineteen years ago, in 2004, after a showing of good cause. Women's-Wisconsin has operated under an unrestricted resident license since that time and without further discipline by any state board of pharmacy or federal authority. The Stipulation is attached for your reference.

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST WALLACE L. SIMONS, R.Ph., WOMEN'S INTERNATIONAL PHARMACY, INC. RESPONDENTS	:	STIPULATION 88 PHM 25, 90 PHM 70 90 PHM 70a, 94 PHM 66 94 PHM 111

It is hereby stipulated between the above Respondents and the undersigned prosecuting attorney for the Division of Enforcement of the Department of Regulation and Licensing, as follows:

1. This Stipulation is entered into as a result of a pending investigation of Respondents by the Division of Enforcement and a hearing in process. The parties consent to the resolution of the above files by agreement and without a conclusion of the ongoing hearing on the formal complaint which has been issued in this matter, or a hearing in 90 PHM 70a, and without any issuance of any other complaints in the other above-named investigations which have been opened with respect to these respondents. This agreement does not resolve the allegations of 95 PHM 25.

2. Respondents understand that by signing this Stipulation, respondents waive the following rights with respect to disciplinary proceedings: the right to a statement of the allegations against respondents; a right to a hearing at which time the State has the burden of proving those allegations; the right to confront and cross-examine the witnesses against respondents; the right to call witnesses on respondents' behalf and to compel attendance of witnesses by subpoena; the right to testify personally; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to respondents under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, and the Wisconsin Administrative Code, except as expressly reserved elsewhere herein.

3. Respondents are aware of respondents' right to seek legal representation and have obtained legal advice before signing this Stipulation.

4. Respondents assure the Board that they have at all times complied with ¶A of the Order, and that they will make every effort to ensure that Genesis Systems Corporation complies with ¶F of the Order but they do not legally control Genesis. Respondents also deny and do not agree that any violations have been committed intentionally or otherwise, except those admitted in the Answer to the Complaint in 88 PHM 25/90 PHM 70, but agree to the adoption of the attached Final Decision and Order by the Board. The parties consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation or the proposed Final Decision and Order, and the matter shall be returned to the Division of Enforcement for further proceedings, including the resumption of the currently ongoing hearings. In the event that this Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties agree that an attorney for the Division of Enforcement may appear before the Board, in open or closed session, without the presence of Respondents or Respondents' attorney, for the purposes of speaking in support of this agreement and answering questions that the members of the Board and its staff may have in connection with their deliberations on the case. Respondents have the option of appearing with the prosecuting attorney at all open or closed sessions, and any appearance shall be preceeded by timely notice.

7. The Board Advisor in this matter may participate freely in any deliberations of the Board regarding acceptance of this Stipulation and the proposed Final Order, and may relate to the Board any knowledge and views of the case acquired during the investigation, the panel session, the hearing and the settlement negotiations.

8. The Division of Enforcement joins respondents in recommending that the Board adopt this Stipulation and issue the attached Final Decision and Order.

9. Respondents are informed that should the Board adopt this stipulation, the board's final decision and order is a public record and will be published in the Monthly Disciplinary Report issued by the department. A summary of the order will be published in the Wisconsin Regulatory Digest issued semiannually by the Board. This is standard department procedure and in no way specially directed at respondents.

10. Respondents do not waive, and may pursue any rights to reimbursement for costs, attorneys' fees, or disbursements, from any state agency, and before any forum. Any such agency may defend such claims on any grounds available. This agreement also does not preclude respondents and their attorneys from pursuing any sanctions arising out of this hearing over which the Pharmacy Examining Board has no jurisdiction.

11. The Division and its prosecuting attorney assure respondents that there are no actual or tacit agreements or understandings with the FDA, DEA, or any other state or federal agency that after the entry of this Order, the FDA, DEA, or other agency will proceed against respondents in the Division's stead, i.e. the Division and its prosecuting attorney have no agreement or understanding with another agency to undermine the finality of this Stipulation and Final Decision and Order. Respondents understand that the FDA and DEA may be conducting their own investigations, and that to the extent that they or other agencies request the cooperation of the Division, such cooperation will be provided only in a manner similar to cooperation routinely provided in other cases.

12. Any patient records, without limit as to form, in any of the above-captioned files kept by the Department of Regulation & Licensing will be released under a public records request only in accordance with §146.82, Wis. Stats. The department will notify respondent of any requests to view or copy any of the file documents received from respondents upon receipt of the request, including the identity of the requestor if known, and at least 30 days before release of any records. This does not limit the department's obligation to comply with §19.35 et seq., Wis. Stats.

13. The parties agree that the wording "Reprinted for educational and promotional purposes..." is substantially similar to the wording set forth in ¶F of the Order.

WOMEN'S INTERNATIONAL PHARMACY, INC., by:

8-16-95

Wallace L. Simons, President — Date
Wallace L. Simons, R.Ph., personally

8/16/95

Howard M. Hoffmann, Attorney for Respondent
Date

8/16/95

Arthur Thexton, Prosecuting Attorney — Date
Division of Enforcement

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	FINAL DECISION AND ORDER
WALLACE L. SIMONS, R.Ph., WOMEN'S INTERNATIONAL PHARMACY, INC. RESPONDENTS	:	88 PHM 25, 90 PHM 70 90 PHM 70a, 94 PHM 66 94 PHM 111

The parties to this action for the purposes of §227.53, Wis. Stats., are:

Wallace L. Simons, R.Ph.
[redacted] Leyton Lane
Madison, WI 53713

Women's International Pharmacy, Inc.
5708 Monona Drive
Madison, WI 53716

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Respondent Wallace L. Simons (dob 7/10/40) is and was at all times relevant to the facts set forth herein a registered pharmacist licensed in the State of Wisconsin pursuant to license #7258. At all times material, respondent Simons was the managing pharmacist of co-respondent Women's International Pharmacy, which was at all times relevant to the facts set forth herein a pharmacy licensed in the State of Wisconsin pursuant to license #7091.

2. The Respondents are charged in 88 PHM 25 and 90 PHM 70 with exceeding the legal limits for compounding and thus being manufacturers, of making certain recordkeeping errors with respect to controlled substances dispensed by them and their staff, and dispensing in a manner inconsistent with state law and the Food Drug & Cosmetic Act. Respondents deny all these allegations, but desire to settle this matter solely to avoid the expenses and uncertainties of litigation.

CONCLUSIONS OF LAW

3. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to §450.10, Wis. Stats. and is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.

4. The Board concludes that respondents did in the past commit errors with respect to their dispensing of compounded testosterone prescriptions by failing to stamp some hard-copy prescriptions for controlled substances with a red "C" although they were combined with non-controlled substance records, failing to keep their hard copy prescription records in chronological order, and dispensing more than a 34 day supply at one time, all in violation of ch. Phar 8, Wis. Adm. Code. The Board has no evidence that such violations continued after June, 1993, when respondents adopted a new recordkeeping system.

5. The Board concludes that routinely dispensing large quantities of compounded drug products to practitioners (except as permitted in this Order) and respondents' providing compounded drug products to Health Pharmacies, Inc. in 1992-93, is not compounding for dispensing to a patient.

6. The Board concludes that if Women's International Pharmacy complies with this Final Decision and Order, its actions to be undertaken under this Order will be in conformance with applicable state and local laws regulating the practice of pharmacy, that it will be regularly engaged in dispensing prescription drugs upon the prescriptions of practitioners licensed to administer such drugs to patients under their care in the course of their professional practice, and that it will not be manufacturing under §450.01(13), Wis. Stats.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that respondents are REPRIMANDED for their actions described in ¶4, above.

IT IS FURTHER ORDERED, that the licenses of Wallace L. Simons, R.Ph., to practice pharmacy, and of Women's International Pharmacy to be a pharmacy are LIMITED in that all compounding performed by either is limited to the following:

A. No compounded drug or drug product shall be dispensed unless all active ingredients are legally obtainable in the United States and of USP or equivalent grade and all inactive ingredients are either food grade or customarily used in the profession.

B. No prescription drug shall be dispensed except directly to a patient in the pharmacy or delivered to a patient's home by an agent of the pharmacist, including a common carrier or the US Postal Service, or pursuant to this Order.

C. No compounded drug product shall be delivered, dispensed, or otherwise transferred to another pharmacy for dispensing to a patient unless respondent has informed that pharmacy that the portion of the medication container label showing the name, address and telephone number of Women's International Pharmacy must appear on the medication container dispensed to the patient, and Women's International Pharmacy makes and documents direct telephone contact with each patient to provide a consultation.

D. No substance shall be delivered, dispensed, or otherwise transferred to a practitioner's office more than once unless the practitioner certifies in writing that in-office administration of the substance to the practitioner's patients is medically necessary, and the quantities of such substance are reasonable under the circumstances to provide only that amount of product which will carry the patient from the time the practitioner administers the drug until a prescription can be presented to, and dispensed by, a pharmacy for that patient. In the absence of other evidence, such a period of time shall be presumed to be ten calendar days. The form of such certification shall be approved by the Board or its designee, which approval shall not be unreasonably withheld. The amount, if any, to be charged by respondents for the above permitted transfer of office supplies is within respondents' discretion. Except as permitted above, respondents shall not provide any "office samples" or other free or reduced-price products to practitioners. Records of office supplies provided to practitioners shall be clearly distinguishable from prescription dispensing records, and shall be readily retrievable and verifiable.

E. Respondents shall compound only the number or quantity of medication called for by the initial-fill quantities stated on the prescriptions respondents have actually received at the time the compounding is commenced, or on the basis of prescriptions respondents have received in the past 30 days. Respondents may, in the case of capsules, round that number up to the number of capsules held by the pharmacy's equipment. Respondents shall not accept, compound or dispense two or more prescriptions for the same formula to the same patient at the same time, in an effort to evade the limitations of this paragraph. All drug products shall be dispensed and labeled with "beyond use" dates of six months from the date of compounding or 25% of the time before the expiration date of any component used in the compounding, whichever is nearer: any medication which will not be so used shall be discarded. Respondents may use any other beyond-use date which can be supported by reasonable stability testing.

F. Respondents shall not provide reprints, articles or other printed materials purporting to state that the active ingredients in respondents' products, or formulae similar to those used by respondents, are safe or effective unless those articles were published in refereed journals. Respondents shall not promote directly or through Genesis Systems Corporation or another, any particular formula or dosage of any drug or drug product which they compound, and shall advise and counsel Genesis Systems Corporation not to so promote. Upon request, respondents shall submit all promotional and informational materials in use at that time (and for the year preceeding the request) to the Board for review by the Board or its designee. Such submission is for informational purposes only. All material intended to be sent to practitioners or patients shall bear the date of printing after 12/1/95. All reprints of articles or similar materials shall bear the disclaimer: "Reprinted for promotional purposes by Genesis Systems Corporation for Women's International Pharmacy" or similar wording, after 12/1/95.

G. Respondents shall provide to any requesting licensed pharmacy (or pharmacist) which a patient desires to use with respondents' complete ingredient list and formula for any prescription which it has compounded for that patient, and shall make no statement concerning price, difficulty, or other issue which could reasonably be interpreted as an attempt to discourage the patient-selected pharmacy or pharmacist from compounding the prescription. If, in the course of transmitting all information necessary to truthfully describe the compounding process, respondents accurately apprise the pharmacy or pharmacist of the complexity of the process, such a statement does not violate this paragraph.

H. All products containing progesterone or any estrogen shall contain a Patient Package Insert containing all FDA-required content no later than August 1, 1995. If, for reasons beyond respondents' control, the PPI cannot be made ready by this date, a reasonable extension shall be granted.

J. Third party claims submitted by respondent may include the NDC numbers of the active ingredients if the claim processor has been informed that the product was compounded, that the NDC numbers refer only to the ingredients and not to the final product, and the processor has consented to the claim being filed in such fashion.

IT IS FURTHER ORDERED, that in 94 PHM 66, a distributor license shall be granted to respondents upon updating the application to answer all questions with currently accurate and complete information.

IT IS FURTHER ORDERED that the complaints in 88 PHM 25, 90 PHM 70, and 90 PHM 70a is DISMISSED and will not be reopened as long as the parties comply with this Stipulation and Final Decision and Order.

IT IS FURTHER ORDERED that 94 PHM 111 is CLOSED without disciplinary action.

IT IS FURTHER ORDERED, that the settlement agreement incorporated into this Order is binding upon respondents and their successors, and upon the Department of Regulation & Licensing and Pharmacy Examining Board and their successors, but without prejudice to the right of the legislature or Board to adopt statutory and administrative rules which may modify or change public policy as to future actions by licensees.

Dated this 16 day of August, 1995.

WISCONSIN PHARMACY EXAMINING BOARD

by: Thomas McGuigan
a member of the board

akt
69

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
WALLACE L. SIMONS, R.Ph.,	:	ORDER REMOVING LIMITATIONS
WOMEN'S INTERNATIONAL PHARMACY, INC., RESPONDENTS.	:	Case Nos. LS 9312291 PHM LS 9405231 PHM

PARTIES

The parties in this matter under section 227.44 of the Statutes and section RL 2.037 of the Wisconsin Administrative Code, and for purposes of review under sec. 227.53, Stats. are:

Disciplinary Authority:
Pharmacy Examining Board
1400 East Washington Ave.
Madison, WI 53703

The board and the division are represented by:

Division of Enforcement
Department of Regulation and Licensing
1400 E. Washington Ave.
Madison, WI 53703

Complainant:
Division of Enforcement
Department of Regulation and Licensing
Madison, WI 53708-8935

Respondents:
Wallace L. Simons, R.Ph.
[redacted] East Dalea Drive
P.O. Box [redacted]
Carefree, AZ 85377

The respondents are represented by:
Nia Enemuoh Trammell
Michael Best & Friedrich, LLP
One South Pinckney St.
Suite 700
Madison, WI 53703

Women's International Pharmacy, Inc.
2 Marsh Ct.
Madison, WI 53718

Howard M. Hoffman
Duane Morris
227 West Monroe St.
Suite 3400
Chicago, IL 60606

On October 13, 2004, the Wisconsin Pharmacy Examining Board reviewed the respondents' petition dated August 5, 2004, requesting that the removal of the limitations in paragraphs A

through J, inclusive, from the board's Final Decision and Order, dated August 16, 1995, case numbers LS 9312291 PHM and LS 9405231 PHM

Based upon the Board's review of the petition and good cause appearing therefore:

IT IS THEREFORE ORDERED: That the limitations in paragraphs A through J, inclusive, of the board's Final Decision and Order, dated August 16, 1995, case numbers LS 9312291 PHM and LS 9405231 PHM, be REMOVED. Wallace L. Simons, license number 7258, is hereby restored to the unlimited practice of pharmacy in the state of Wisconsin, with all right, title and privilege appurtenant thereto. Women's International Pharmacy, license number 7091, is hereby restored to the unlimited practice of pharmacy in the state of Wisconsin, with all right, title and privilege appurtenant thereto.

Dated : October 13, 2004

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

by _____
Michael Bettiga, R.Ph.
Chairman

wlpUNLIMITED9-28-04

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Women's International Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH01886

Physical Address: 12012 N 111th Ave

City: Youngtown State: AZ Zip: 85363

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 623-214-7700 Toll Free # (NAC 639.708, NRS 639.23286): 800-699-8143

Fax: 800-330-0268 Contact Email: smogen@womensinternational.com

Website: www.womensinternational.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Susan Mogen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21052

Name of Person with direct knowledge of compounding procedures: Susan Mogen, RPh PIC

Email of Person with direct knowledge of compounding procedures: smogen@womensinternational.com

Telephone of Person with direct knowledge of compounding procedures: 623-214-7700 x 1531 or 800-699-8143

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See attachment 1

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Stability testing that includes API potency, particulate matter, appearance, pH (if applicable), endotoxin, assay for preservative, container closure, sterility, and AET testing at every timepoint. Timepoints include T0, T30, T60, T90, T120.

6. What laboratory performs this additional testing?
Name: ARL BioPharma
Address: 840 Research Pkwy #546
City: Oklahoma City State: OK Zip: 73104
Telephone: 405-271-1144

7. What is your procedure for visual inspection of compounded sterile products?
Every vial of every batch is visually inspected by qualified quality personnel only. Must meet an acceptance criteria to move forward with release.

8. How often do you perform glove fingertip and medial fill testing?
Quarterly

9. What is your policy if an employee fails a glove fingertip or media-fill test?
If an operator has failed the media fill it must be repeated entirely. Media fill failures must be investigated by the quality unit and may result in operator retraining or disqualification at the discretion of the quality unit and the PIC. Organisms must be identified to the species level.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial:
Read and understand SOP's, hands on training, aseptic technique competency, media fill, garb Qualification, cleaning competency.

Annual:
Potency testing, hazardous communication training, cleaning competency.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaners used: Peridox RTU, Sterile 70% IPA, Steri-Perox 6%.
Daily AM: PECs, powderhoods, scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks - PeridoxRTU followed by sIPA wipe.
Daily PM: PECs, powderhoods - PeridoxRTU followed by sIPA wipe.
Daily PM: scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks. - Steri-perox 6% follwed by sIPA wipe.
Weekly PM: PECs, passthroughs, sinks, hot plates, floors, powderhood, carts, tabletops, scales, trash cans, repeater pumps - PeridoxRTU followed by sIPA wipe.
Monthly PM: Entire room ceiling, walls to floors and everything in the room - PeridoxRTU followed by sIPA wipe.

12. Who performs the sterile compounding process at your facility?
Sterile compounding technicians, sterile compounding Pharmacist.

13. Who is responsible and accountable for the sterile compounding process at your facility?
Sterile Compounding Manager- Matt Thorpe, Rph
Pharmacist in Charge- Susan Mogen, Rph

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Room temperature, Refrigerated, Frozen.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Biological safety cabinets, Laminar airflow workbench, Powder containment hoods.		
2. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
7. If yes, list the name of the device: N/A		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? HAZARDOUS DRUG: Observe special handling and disposal requirements. Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have any questions about the best way to dispose of medications. There may be a drug take-back program in your area. If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Hazardous communication training (Safety procedures and hazardous communication SOP), USP <800> powerpoint training.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

See attachment 1

2. What sterilization methods are utilized at your facility?

Sterilization via filtration.

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:

A biological indicator must be placed in the coldest part of the chamber (based on temperature mapping) and run with every autoclave cycle load. The BI serves as an additional challenge to the sterilization process. A positive control will be placed in the incubator once daily.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Mogen

Name of Person who Completed the Form

Pharmacist in charge

Title

Susan L Mogen

Signature (copies or stamps not accepted)

10-3-23

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

ATTACHMENT 1

WOMEN'S INTERNATIONAL PHARMACY INITIAL STERILE FORMULARY

Gonadorelin Acetate 0.2 mg/ml

Methylcobalamin 10 mg/ml

NAD+ 200 mg/ml

Sermorelin Acetate 2 mg/ml

Testosterone Cypionate/Anastrozole 200/0.5 mg/ml Grapeseed oil

Testosterone Cypionate/Anastrozole 200/1 mg/ml Grapeseed oil

Testosterone Cypionate/Dhea 200/10 mg/ml Grapeseed oil

Testosterone Cypionate/Dhea 50/5 mg/ml Grapeseed oil

Alprostadil 100 mcg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 6 mcg/15 mg/0.25 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 8.3 mcg/22.5mg/0.83 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 10 mcg/30 mg/1 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 10 mcg/30 mg/4 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 20 mcg/30 mg/2 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 40 mcg/30 mg/4 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 60 mcg/30 mg/6 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 100 mcg/30 mg/6 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/1 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/4 mg/ml

Phenylephrine HCl 1 mg/ml

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Women's International Pharmacy, Inc.
Address :	12012 N 111th Ave Youngtown AZ 85363
Registration No :	Y008610
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	04/08/2021
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

ENTITY INFORMATION

Entity Details

Entity Name:	WOMEN'S INTERNATIONAL PHARMACY, INC.	**Entity ID:**	F09947387
Entity Type:	Foreign For-Profit (Business) Corporation	**Entity Status:**	Active
Formation Date:	8/4/2001	**Reason for Status:**	In Good Standing
Approval Date:	7/25/2018	**Status Date:**	9/13/2019
Original Incorporation Date:	8/4/2001	**Life Period:**	Perpetual
Business Type:	Other - RETAIL PHARMACY	**Last Annual Report Filed:**	2023
Domicile State:	Wisconsin	**Annual Report Due Date:**	8/4/2024
		Years Due:	
Original Publish Date:	8/29/2001		

Pending Document

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ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/12/2022
Receipt Number: 2022132497
Receipt Amount $: 480.00

Pharmacy - Independent

Compounding – Non-Sterile,Retail

	PERMIT NO	**EXPIRES**
	Y008610	**10/31/2024**
Issued to :	Women's International Pharmacy, Inc. Women's International Pharmacy, Inc. 12012 N 111TH AVE YOUNGTOWN, AZ 85363	Women's International Pharmacy, Inc. 12012 N 111TH AVE YOUNGTOWN, AZ 85363

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Women's International Pharmacy, Inc.
LICENSE NUMBER : Y008610
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

10008475 2/002227-1/1-0

255/656 1:5

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0066856	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0066856	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

Ownership Information for Women's International Pharmacy, Inc. 12012 N. 111th Ave., Youngtown, AZ 85363

Women's International Pharmacy, Inc.
2 Marsh Ct.
Madison, WI 53718

Officers and Directors of Women's International Pharmacy, Inc.:

- Robert J. Kilgore, CEO and President
  231 Violet Street, Suite 140
  Golden, CO 80401
  [redacted]

- David P. Malm, Secretary, Treasurer and Director
  220 Boylston Street, # 9009
  Boston, MA 02116
  [redacted]

Women's International Pharmacy is wholly owned by Belmar MidCo, Inc.

Belmar MidCo, Inc.
231 Violet St., Ste 100
Golden, CO 80401
(720) 531-5364

Officers and Directors of Belmar MidCo, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director

Belmar Midco, Inc. is wholly owned by Belmar Holdings, Inc.:

Belmar Holdings, Inc.
c/o Webster Equity Partners
1000 Winter Street
Waltham, MA 02451
Attn: David Malm

Officers and Directors of Belmar Holdings, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director
- W. Brandon Ingersoll, Director
- Doug Williams, Director
- David W. Hill, Director
- Dr. Angela DeRosa, Director
- Matt Beer, Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Women's International Pharmacy, Inc.

Pharmacy/Wholesaler License # (if applicable): PH01886

Physical Address: 12012 N. 111th Ave.

City: Youngtown State: AZ Zip: 85363

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 1-800-699-8143 Website: www.womensinternational.com

Licensing Company Email: michelle.violi@belmarpharma.com

Section 2: Personal Information

First: Susan Middle: Last: Mogen

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted] N 68th Ave

City: Glendale State: AZ Zip: 85308

Telephone: [redacted] Email: smogen@womensinternational.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South Dakota State University		08/1983 - 05/1988	
Address	City	State	Zip
1175 Medary Ave	Brookings	SD	57007
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Irene School		08/1970 - 05/1983	
Address	City	State	Zip
130 State St	Irene	SD	57037
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2002 - present	[redacted]	Glendale	AZ	85308
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Women's International Pharmacy			06/1997 - present	
Business Address		**City**	**State**	**Zip**
12012 N 111th Ave		Youngtown	AZ	85363
Phone	**Title**		**Number of Employed Hours**	
623-214-7700	Staff Pharmacist/Pharmacist Manager (Lab Manager)/Pharmacist in charg		40 hours/wk = 6000+	
Description of Duties				
Staff pharmacist in dispensing area - verification of Rx, receive prescriber/patient phone calls/VM; Pharmacist manager - oversee dispensing area, Lab manager - oversee non-sterile compounding lab; Pharmacist in charge- compliance/regulat				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens Pharmacy			06/1988 - 06/1997	
Business Address		**City**	**State**	**Zip**
4344 W Cactus Rd		Glendale	AZ	85304
Phone	**Title**		**Number of Employed Hours**	
	Staff Pharmacist/Pharmacist in charge		40 hours/week = 6000+	
Description of Duties				
Filling and verification of prescription orders, receive prescriber/patient phone calls; patient counseling; inventory; compliance/regulation				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. **A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

No additional information required/necessary for questions 1-10

Original Signature (electronic, copies or stamps not accepted)

01/24/2024
Date

I, Susan Mogen, **certify that as the designated representative for**

Women's International Pharmacy, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. sm I am at least 21 years of age;
3. sm I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. sm I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. sm I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. sm I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. sm I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Susan Mogen

Print Name (First, Last)

Susan L Mogen

Original Signature (electronic, copies or stamps not accepted)

01/24/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Mogen

Print Name (First, Last)

Susan L Mogen

Original Signature (electronic, copies or stamps not accepted)

01/24/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Susan Mogen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Susan L Mogen

Original Signature

01/24/2024

Date

Subscribed and Sworn to before me this 24th day of January.

Jennifer Roseberry

Notary Public Signature

JENNIFER J. ROSEBERRY
Notary Public - State of Arizona
MARICOPA COUNTY
Commission # 659093
Expires November 11, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Women's International Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH01886

Physical Address: 12012 N 111th Ave

City: Youngtown State: AZ Zip: 85363

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 623-214-7700 Toll Free # (NAC 639.708, NRS 639.23286): 800-699-8143

Fax: 800-330-0268 Contact Email: smogen@womensinternational.com

Website: www.womensinternational.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Susan Mogen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 21052

Name of Person with direct knowledge of compounding procedures: Susan Mogen, RPh PIC

Email of Person with direct knowledge of compounding procedures: smogen@womensinternational.com

Telephone of Person with direct knowledge of compounding procedures: 623-214-7700 x 1531 or 800-699-8143

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☐ Low ☐ Medium ■ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
See attachment 1

4. Will you be utilizing beyond use dates in excess of USP-797? ■ Yes ☐ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
Stability testing that includes API potency, particulate matter, appearance, pH (if applicable), endotoxin, assay for preservative, container closure, sterility, and AET testing at every timepoint. Timepoints include T0, T30, T60, T90, T120.

6. What laboratory performs this additional testing?
Name: ARL BioPharma
Address: 840 Research Pkwy #546
City: Oklahoma City State: OK Zip: 73104
Telephone: 405-271-1144

7. What is your procedure for visual inspection of compounded sterile products?
Every vial of every batch is visually inspected by qualified quality personnel only. Must meet an acceptance criteria to move forward with release.

8. How often do you perform glove fingertip and medial fill testing?
Quarterly

9. What is your policy if an employee fails a glove fingertip or media-fill test?
If an operator has failed the media fill it must be repeated entirely. Media fill failures must be investigated by the quality unit and may result in operator retraining or disqualification at the discretion of the quality unit and the PIC. Organisms must be identified to the species level.

10. Describe your initial and annual training program for all personnel performing sterile compounding:
Initial:
Read and understand SOP's, hands on training, aseptic technique competency, media fill, garb Qualification, cleaning competency.

Annual:
Potency testing, hazardous communication training, cleaning competency.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Cleaners used: Peridox RTU, Sterile 70% IPA, Steri-Perox 6%.
Daily AM: PECs, powderhoods, scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks - PeridoxRTU followed by sIPA wipe.
Daily PM: PECs, powderhoods - PeridoxRTU followed by sIPA wipe.
Daily PM: scales, tabletops, repeater pumps, carts, passthroughs, hot plates, sinks. - Steri-perox 6% follwed by sIPA wipe.
Weekly PM: PECs, passthroughs, sinks, hot plates, floors, powderhood, carts, tabletops, scales, trash cans, repeater pumps - PeridoxRTU followed by sIPA wipe.
Monthly PM: Entire room ceiling, walls to floors and everything in the room - PeridoxRTU followed by sIPA wipe.

12. Who performs the sterile compounding process at your facility?
Sterile compounding technicians, sterile compounding Pharmacist.

13. Who is responsible and accountable for the sterile compounding process at your facility?
Sterile Compounding Manager- Matt Thorpe, Rph
Pharmacist in Charge- Susan Mogen, Rph

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Room temperature, Refrigerated, Frozen.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Biological safety cabinets, Laminar airflow workbench, Powder containment hoods.		
2. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
7. If yes, list the name of the device: N/A		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? HAZARDOUS DRUG: Observe special handling and disposal requirements. Do not flush down a toilet or pour down a drain. Check with your pharmacist if you have any questions about the best way to dispose of medications. There may be a drug take-back program in your area. If an overdose is suspected contact your local poison control center at 1-800-222-1222 or go to the nearest emergency room.		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs? Hazardous communication training (Safety procedures and hazardous communication SOP), USP <800> powerpoint training.		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:
See attachment 1

2. What sterilization methods are utilized at your facility?
Sterilization via filtration.

3. Does your facility utilize biological indicators? ■ Yes ☐ No

4. If yes, describe how they are utilized:
A biological indicator must be placed in the coldest part of the chamber (based on temperature mapping) and run with every autoclave cycle load. The BI serves as an additional challenge to the sterilization process. A positive control will be placed in the incubator once daily.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Susan Mogen
Name of Person who Completed the Form

Pharmacist in charge
Title

Susan L Mogen
Signature (copies or stamps not accepted)

10-3-23
Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

ATTACHMENT 1

WOMEN'S INTERNATIONAL PHARMACY INITIAL STERILE FORMULARY

Gonadorelin Acetate 0.2 mg/ml

Methylcobalamin 10 mg/ml

NAD+ 200 mg/ml

Sermorelin Acetate 2 mg/ml

Testosterone Cypionate/Anastrozole 200/0.5 mg/ml Grapeseed oil

Testosterone Cypionate/Anastrozole 200/1 mg/ml Grapeseed oil

Testosterone Cypionate/Dhea 200/10 mg/ml Grapeseed oil

Testosterone Cypionate/Dhea 50/5 mg/ml Grapeseed oil

Alprostadil 100 mcg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 6 mcg/15 mg/0.25 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 8.3 mcg/22.5mg/0.83 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 10 mcg/30 mg/1 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 10 mcg/30 mg/4 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 20 mcg/30 mg/2 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 40 mcg/30 mg/4 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 60 mcg/30 mg/6 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 100 mcg/30 mg/6 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/1 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/4 mg/ml

Phenylephrine HCl 1 mg/ml

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Women's International Pharmacy, Inc.
Address :	12012 N 111th Ave Youngtown AZ 85363
Registration No :	Y008610
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	04/08/2021
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

ENTITY INFORMATION

Entity Details

Entity Name:	WOMEN'S INTERNATIONAL PHARMACY, INC.	**Entity ID:**	F09947387
Entity Type:	Foreign For-Profit (Business) Corporation	**Entity Status:**	Active
Formation Date:	8/4/2001	**Reason for Status:**	In Good Standing
Approval Date:	7/25/2018	**Status Date:**	9/13/2019
Original Incorporation Date:	8/4/2001	**Life Period:**	Perpetual
Business Type:	Other - RETAIL PHARMACY	**Last Annual Report Filed:**	2023
Domicile State:	Wisconsin	**Annual Report Due Date:**	8/4/2024
		Years Due:	
Original Publish Date:	8/29/2001		

Pending Document

No Records Found

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Ownership Information for Women's International Pharmacy, Inc. 12012 N. 111th Ave., Youngtown, AZ 85363

Women's International Pharmacy, Inc.
2 Marsh Ct.
Madison, WI 53718

Officers and Directors of Women's International Pharmacy, Inc.:

- Robert J. Kilgore, CEO and President
  231 Violet Street, Suite 140
  Golden, CO 80401
  (720) 930-1064
  SSN: 370-86-3204
  DOB: 08/24/1965

- David P. Malm, Secretary, Treasurer and Director
  220 Boylston Street, # 9009
  Boston, MA 02116
  (617) 312-7618
  SSN: 025-46-2400
  DOB: 07/04/1964

Women's International Pharmacy is wholly owned by Belmar MidCo, Inc.

Belmar MidCo, Inc.
231 Violet St., Ste 100
Golden, CO 80401
(720) 531-5364

Officers and Directors of Belmar MidCo, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director

Belmar Midco, Inc. is wholly owned by Belmar Holdings, Inc.:

Belmar Holdings, Inc.
c/o Webster Equity Partners
1000 Winter Street
Waltham, MA 02451
Attn: David Malm

Officers and Directors of Belmar Holdings, Inc.:

- Robert Kilgore, CEO and President
- David P. Malm, Secretary, Treasurer and Director
- W. Brandon Ingersoll, Director
- Doug Williams, Director
- David W. Hill, Director
- Dr. Angela DeRosa, Director
- Matt Beer, Director

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Gonadorelin Acetate 0.2 mg/ml

Methylcobalamin 10 mg/ml

NAD+ 200 mg/ml

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Testosterone Cypionate/Dhea 200/10 mg/ml Grapeseed oil

Testosterone Cypionate/Dhea 50/5 mg/ml Grapeseed oil

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Alprostadil/Papaverine HCl/Phentolamine Mesylate 60 mcg/30 mg/6 mg/ml

Alprostadil/Papaverine HCl/Phentolamine Mesylate 100 mcg/30 mg/6 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/1 mg/ml

Papaverine HCl/Phentolamine Mesylate 30/4 mg/ml

Phenylephrine HCl 1 mg/ml

Ownership Information for Women's International Pharmacy, Inc. 12012 N. 111th Ave., Youngtown, AZ 85363

Women's International Pharmacy, Inc.
2 Marsh Ct.
Madison, WI 53718

Officers and Directors of Women's International Pharmacy, Inc.:

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- David P. Malm, Secretary, Treasurer and Director
- W. Brandon Ingersoll, Director
- Doug Williams, Director
- David W. Hill, Director
- Dr. Angela DeRosa, Director
- Matt Beer, Director

ENTITY INFORMATION

Entity Details

Entity Name:	WOMEN'S INTERNATIONAL PHARMACY, INC.	**Entity ID:**	F09947387
Entity Type:	Foreign For-Profit (Business) Corporation	**Entity Status:**	**Active**
Formation Date:	8/4/2001	**Reason for Status:**	In Good Standing
Approval Date:	7/25/2018	**Status Date:**	9/13/2019
Original Incorporation Date:	8/4/2001	**Life Period:**	Perpetual
Business Type:	Other - RETAIL PHARMACY	**Last Annual Report Filed:**	2023
Domicile State:	Wisconsin	**Annual Report Due Date:**	8/4/2024
		Years Due:	
Original Publish Date:	8/29/2001		

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ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 09/12/2022
Receipt Number: 2022132497
Receipt Amount $: 480.00

Pharmacy - Independent

Compounding – Non-Sterile,Retail

	PERMIT NO	**EXPIRES**
	Y008610	**10/31/2024**
Issued to :	Women's International Pharmacy, Inc. Women's International Pharmacy, Inc. 12012 N 111TH AVE YOUNGTOWN, AZ 85363	Women's International Pharmacy, Inc. 12012 N 111TH AVE YOUNGTOWN, AZ 85363

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Women's International Pharmacy, Inc.
LICENSE NUMBER : Y008610
EXPIRES : 10/31/2024

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

10008475 2/002227-1/1-0

255/656 1:5

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0066856	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FW0066856	05-31-2024	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	03-16-2021

WOMEN'S INTERNATIONAL PHARMACY, INC.
12012 N 111TH AVE
YOUNGTOWN, AZ 85363-1339

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	Women's International Pharmacy, Inc.
Address :	12012 N 111th Ave Youngtown AZ 85363
Registration No :	Y008610
Permit Type :	Pharmacy
Sub Type :	Independent
Date Issued :	04/08/2021
Expiration Date :	10/31/2024
Status :	OPEN
Discipline :	No

Kam Gandhi

Kam Gandhi

® National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP and the United States boards of pharmacy and for internal use by the named facility for VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	758539		**Inspection Information**
Legal Business Name:	Women's International Pharmacy Inc	**Conference Call Date:**	10/16/2023
Doing Business As (DBA):	N/A	**Start Time: 24-hour format (13:00)**	17:00
Address:	12012 North 111th Ave	**End Time: 24-hour format (13:00)**	19:40
City:	Youngtown	**Onsite Inspection Date:**	10/19/2023
State:	AZ	**Start Time: 24-hour format (13:00)**	8:00
Zip Code:	85363	**End Time: 24-hour format (13:00)**	17:10
Telephone number:	623-214-7700	**Inspector Name:**	Ronnie Higgins RPh
Toll free number:	800-699-8143	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	800-330-0268	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.womensinternational.com	**Observer Name/Affiliation (if applicable):**	N/A

Pharmacy Hours of Operation	**Check if 24/7** ☐		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	**(X)**
Sunday			X
Monday	8:00	18:00	
Tuesday	8:00	18:00	
Wednesday	8:00	18:00	
Thursday	8:00	18:00	
Friday	8:00	18:00	
Saturday	9:00	12:00	

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Susan Mogen	smogen@womensinternational.com	364615
Nonsterile Compounding Supervisor	Kari Anne Berthold	kberthold@womensinternational.com	1148175
Sterile Compounding Supervisor	Matthew Thorpe	mthorpe@womeninternational.com	857398
Hazardous Compounding Supervisor	Susan Mogen	smogen@womensinternational.com	364615

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Susan Mogen	PIC	Y
2	Dana Larson	Quality Manager	N/A
3	Greg Rockers	VP of Strategic and Integration	N/A
4	Matt Thorpe	Sterile Lab Manager	Y
5	Kari Anne Berthold	Non-Sterile Lab Manager	Y
6	Elmer Mares-Morales	Pharmacy Manager	Y
7	Arielle Bailey	Sterile Compounding Technician	Y
8	Cheryl Grabo	Non-Sterile Compounding Technician	Y
9	Megan Nixon-Sandberg	Non-Sterile Compounding Technician	Y
10	Michele Corrigan	Non-Sterile Compounding Technician	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present. Katie Lund- Pharmacist Brandon Swift- Shipping Clerk 7 additional pharmacists, 18 additional technicians, and 6 additional personnel.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
Arizona State Board of Pharmacy	Women's International Pharmacy Inc	Pharmacy/Y008610	10/31/2024
USDOJ/DEA	Women's International Pharmacy Inc	Controlled Substance/Retail Pharmacy/FW0066856	5/31/2024

Inspector Notes: List states in which Non-Resident licenses are held Licensed in all States except MA See Doc01 This pharmacy conducts both sterile and non-sterile compounding for bioidentical hormone replacement. This pharmacy does not dispense insulin and only purchases commercially available drugs from AmerisourceBergen or Anda. The pharmacy has not purchased or compounded with Semaglutide.

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Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
Doc00_PI_WomensInternationalPharmacyInc_Youngstown_AZ	List of Attachments

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy		Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research	X	Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	X
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	X

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	17,545	Total Pharmacists:	12
Nonsterile Compounding Room size:	1181	Number of Compounding Pharmacists	6 (2 sterile)
Nonsterile Compounding powder hoods number:	3	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	1746	Total Student Interns:	0
Nonsterile HD Compounding BSC/CACI hoods number:	4	Total Technicians:	24
Sterile Compounding Ante Room size:	212	Number of Compounding Technicians	12 (3 sterile)
Sterile Compounding Clean/Buffer Room size:	391	Of technicians, how many are certified?	23
Sterile Compounding Number LAFW hoods/areas:	4	Of technicians, how many are techs-in-training?	1
Sterile Compounding Number BSC hoods:	3	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	5
Negative Pressure Sterile HD Room size:	391	Ratio #tech:#RPh present at time of inspection:	22:11
Sterile HD Compounding Number of BSC hoods:	7	Total Pharmacist Hours Per Week:	480
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	960

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	360	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	35%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	98%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	1%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	88%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.			
States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)	1	0	Week of 9/18/23 to 9/23/23
Alaska (AK)	14	0	Week of 9/18/23 to 9/23/23
Arizona (AZ)	189	0	Week of 9/18/23 to 9/23/23
Arkansas (AR)	3	0	Week of 9/18/23 to 9/23/23
California (CA)	508	0	Week of 9/18/23 to 9/23/23
Colorado (CO)	32	0	Week of 9/18/23 to 9/23/23
Connecticut (CT)	9	0	Week of 9/18/23 to 9/23/23
Delaware (DE)	1	0	Week of 9/18/23 to 9/23/23
District of Columbia (DC)	2	0	Week of 9/18/23 to 9/23/23
Florida (FL)	14	0	Week of 9/18/23 to 9/23/23
Georgia (GA)	5	0	Week of 9/18/23 to 9/23/23
Hawaii (HI)	14	0	Week of 9/18/23 to 9/23/23
Idaho (ID)	17	0	Week of 9/18/23 to 9/23/23
Illinois (IL)	11	0	Week of 9/18/23 to 9/23/23
Indiana (IN)	4	0	Week of 9/18/23 to 9/23/23
Iowa (IA)	4	0	Week of 9/18/23 to 9/23/23
Kansas (KS)	1	0	Week of 9/18/23 to 9/23/23
Kentucky (KY)	0	0	Week of 9/18/23 to 9/23/23
Louisiana (LA)	20	0	Week of 9/18/23 to 9/23/23
Maine (ME)	8	0	Week of 9/18/23 to 9/23/23
Maryland (MD)	2	0	Week of 9/18/23 to 9/23/23
Massachusetts (MA)	20	0	Week of 9/18/23 to 9/23/23
Michigan (MI)	6	0	Week of 9/18/23 to 9/23/23
Minnesota (MN)	1	0	Week of 9/18/23 to 9/23/23
Mississippi (MS)	1	0	Week of 9/18/23 to 9/23/23
Missouri (MO)	5	0	Week of 9/18/23 to 9/23/23
Montana (MT)	3	0	Week of 9/18/23 to 9/23/23

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Nebraska (NE)	4	0	Week of 9/18/23 to 9/23/23
Nevada (NV)	39	0	Week of 9/18/23 to 9/23/23
New Hampshire (NH)	2	0	Week of 9/18/23 to 9/23/23
New Jersey (NJ)	2	0	Week of 9/18/23 to 9/23/23
New Mexico (NM)	25	0	Week of 9/18/23 to 9/23/23
New York (NY)	15	0	Week of 9/18/23 to 9/23/23
North Carolina (NC)	12	0	Week of 9/18/23 to 9/23/23
North Dakota (ND)	3	0	Week of 9/18/23 to 9/23/23
Ohio (OH)	4	0	Week of 9/18/23 to 9/23/23
Oklahoma (OK)	3	0	Week of 9/18/23 to 9/23/23
Oregon (OR)	60	0	Week of 9/18/23 to 9/23/23
Pennsylvania (PA)	13	0	Week of 9/18/23 to 9/23/23
Rhode Island (RI)	3	0	Week of 9/18/23 to 9/23/23
South Carolina (SC)	3	0	Week of 9/18/23 to 9/23/23
South Dakota (SD)	0	0	Week of 9/18/23 to 9/23/23
Tennessee (TN)	6	0	Week of 9/18/23 to 9/23/23
Texas (TX)	4	0	Week of 9/18/23 to 9/23/23
Utah (UT)	6	0	Week of 9/18/23 to 9/23/23
Vermont (VT)	15	0	Week of 9/18/23 to 9/23/23
Virginia (VA)	6	0	Week of 9/18/23 to 9/23/23
Washington (WA)	154	0	Week of 9/18/23 to 9/23/23
West Virginia (WV)	1	0	Week of 9/18/23 to 9/23/23
Wisconsin (WI)	17	0	Week of 9/18/23 to 9/23/23
Wyoming (WY)	3	0	Week of 9/18/23 to 9/23/23
Other:	Guam-1	0	Week of 9/18/23 to 9/23/23

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If yes, list the pharmacist on duty*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite*	Yes	Between 40-50. Also the PIC for TX.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes list*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	Per PIC Mogen
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe*	Yes	Quick refill on the website
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	No photos taken
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		All personnel listed on the pharmacy information module by name were interviewed.
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states*	Yes	Only upon patient request and less than 1% in and outside of AZ.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states*	No	Per PIC Mogen
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	No distribution per PIC Mogen.

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Facility Name: Women's International Pharmacy Inc
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Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed door pharmacy, expired licenses, etc.*	Yes	See Doc 01
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	5/1/2024 and inspected approximately every 18 months.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	Per PIC Mogen
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	Yes	CA on 9/27/2023 and conducted annually See Doc 02
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	Per PIC Mogen
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	Per PIC Mogen
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	Per PIC Mogen
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	Per PIC Mogen

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Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	Was visited by the FDA in 2014. No 483.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and select most recent date of survey.*	No	Per PIC Mogen
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	Yes	PCAB was relinquished voluntarily to obtain NABP Compounding Accreditation.
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	Per PIC Mogen
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Onsite for 8 years and then shredded.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how and they are stored on site?*	Yes	Onsite for 8 years and then shredded.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	E-scripts for controls are printed out. Non-control e-scripts are maintained electronically. All paper records are maintained for 8 years. Electronic records are indefinitely maintained at the present time.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Maintained electronically
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	No	Can inactive a prescription but cannot delete a prescription in LifeFile.

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e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	No off site storage.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	N/A	Stated in P&Ps and most stringent laws/rules are loaded into the LifeFile system.
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	PIC Mogen conducts primary source verification on a quarterly basis.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	PIC Mogen conducts primary source verification on a quarterly basis.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification.* *If yes, list certifications and if current?*	N/A	Per PIC Mogen
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state.* *Indicate ratio used and the maximum number of staff who were at the store time.*	N/A	AZ no longer has a pharmacist to tech ratio per Ms Larson.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Standard alarm system that includes motion detectors, glass breakage, door contacts and cameras.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	Pharmacy does not stock or dispense C-IIs.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Pharmacists would maintain the security of the drugs until they could be moved to a secure location.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked.* *If no, document with photo.*	Yes	

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Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site*	N/A	No destruction onsite
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used*	Yes	123 Compliant Logistic is the reverse distributor.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used*	No	Disposed of in regular trash.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe*	Yes	Private conference room as you enter the pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection*	Yes	Alarm settings are a low of 68 degrees F and a high of 77 degrees F. Temperature at time of inspection was 69.79 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Continuous monitoring by enteliWEB.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions alerted? How long are records maintained?*	Yes	Alarm settings are a low of 2 degrees C and a high of 8 degrees C.

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Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	3.15 degrees C at time of inspection.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen items in general pharmacy.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	No back-up power. In process of looking to purchase a generator per PIC Mogen.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	In process of securing a maintenance contract per PIC Mogen.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	Quality and pharmacists would conduct a product assessment of each item.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	This is a corporate function.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information and circumstances leading to the purchase.*	No	Per PIC Mogen

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *(or non-manufacturer sources)*	Yes	ABC and Anda.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Unknown	This is a corporate function.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors and look for diversions in the supply chain?)*	Unknown	This is a corporate function.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	Corporate function
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	Corporate function
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The item would be quarantined and Quality would conduct an investigation.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	Per Ms Larson
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *I assume to all purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	Corporate function
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	Per Ms Larson
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA 222 forms?*	N/A	No C-IIs
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who is signing orders in CSOS?*	N/A	No C-IIs

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		Finding	Notes
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	No C-IIs
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	Per PIC Mogen
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchased (plant name and license of other entity).*	No	Per PIC Mogen
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory of drugs, audit trail used, perpetual inventory in computer, etc.).*	Yes	Perpetual inventory of all items.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies (law enforcement to whom reports are made).*	Yes	No diversion but would contact the local authorities and notify the AZ Board of Pharmacy.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	No C-IIs
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	No C-IIs
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Last inventory on 5/1/2023 and inventory is taken annually.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	Per PIC Mogen
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

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		Finding	Notes
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types*	No	Per PIC Mogen
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	At least every other week.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Pull 30 days in advance.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	Per PIC Mogen
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	Per PIC Mogen
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	Sent for destruction.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Information is entered by a technician and updated with each patient contact.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how it is indicated in the system the prescription is a veterinary prescription?*	N/A	No animal dispensing.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	

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		Finding	Notes
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process*	Yes	Contact the prescriber and if fraudulent would contact the local authorities.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Verification of patient and prescribers address and if any question, they contact the prescriber.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom*	Yes	Pharmacist verifies the prescription is entered correctly.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	Manual DUR takes place when the pharmacist is conducting the verification of data entered by the technicians and also at final verification of the prescription.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR*	No	Reviewed 6 patient profiles 4 had no allergies and 5 had no disease states/medical conditions, none of the 6 had prescriptions from other pharmacies or OTCs.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe*	No	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe*	Yes	Daily per PIC Mogen

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		Finding	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	At the pharmacist discretion
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability*	Yes	Hard halt and only a pharmacist can override and this is documented in the LifeFile system.
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	No	No drug database in LifeFile per PIC Mogen.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	All DURs are manual.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary practice electronic database used. If not, list resource used for performing manual DUR.*	N/A	No animal dispensing.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, if written, and how documented.*	Yes	The pharmacist conducts a final check on the prescription prior to sending the prescription to shipping.
69.00	Are filled prescriptions appropriately labeled? *Cite rule.*	Yes	As required by State Law.
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record review/audit of pharmacy computer system user.*	Yes	LifeFile
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	Shred-It picks up these items monthly.
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Unknown	While packaging suppositories the vial containing the suppositories was placed directly in contact with the ice bricks.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	Per PIC Mogen

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		Finding	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	Per PIC Mogen
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are they stored, non-patient specific.*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	Per PIC Mogen
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are they stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer."*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer."*	Yes	Receptionist

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		Finding	Notes
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Toll free number provided and printed information
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Toll free number provided and printed information
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	The pharmacy has printed their own PPI and provides these to the patient.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	As provided by the manufacturer
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as Clozapine, Isotretinoin, or Thalidomide).*	N/A	No REMS drugs
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	In the pharmacy system, counseling is documented electronically. Documented in the computer system for mailed or delivered prescriptions.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state.* *Describe how (such as patient contact information and hours of inspection).*	No	
85.00	Are processes in place to handle a drug recall?	Yes	No recalls lately
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	

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		Finding	Notes
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program*	Yes	This is Ms Larson's responsibility.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both*	Yes	Electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Monthly
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if are unintervened forms on hard copy or electronic*	Yes	Electronic

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		Finding	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	This is a corporate function with any event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	No drug formulary.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Monthly
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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		Finding	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported or stating if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	To MedWatch if required.
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	No devices.
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	Random consumer surveys.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Nonsterile Compounding Inspection

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		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	No	Reviewed 6 patient profiles 4 had no allergies and 5 had no disease states/medical conditions, none of the 6 had prescriptions from other pharmacies or OTCs.
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	All copies of commercially available items are in a different oil or different base and documented on most of the prescriptions reviewed.
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes	
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	Yes	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	Only by patient request.
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	Only by patient request.
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	Per RPh Berthold
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	No	Per RPh Berthold
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	No	Per RPh Berthold
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	Yes	Corporate marketing department
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds promoted.*	No	Per PIC Mogen
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds promoted.*	N/A	

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Nonsterile Compounding Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
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		Finding	Notes
2.06	If yes, are any of these controlled substances? *List compounds provided.*	N/A	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	Per PIC Mogen
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide list.*	Yes	Tablets, capsules, suspensions, troches and lozenges
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List*	Yes	Creams, gels and suppositories
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List*	No	Per RPh Berthold
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list*	No	Per RPh Berthold
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	Per RPh Berthold
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	No	Any commercially available item that is being compounded is either in a different oil or different base. 0%
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	N/A	
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	N/A	
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	No	0%

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		Finding	Notes
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	80%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	Yes	20%
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	80-85%
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	Printed at the entrance to the prescription department and electronically on each laptop.
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding*	Yes	35%
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs*	Yes	Medisca, Letco, Spectrum and RLC Labs (SP Labs)

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		Finding	Notes
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*	Yes	This is done both at the corporate level and at the pharmacy from the FDA website.
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate source*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain*	Yes	PK software system
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	No	
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed*	Yes	ARI for potency
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List make(s), type and model number*		See Doc 03
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and calibrate frequency*	Yes	Manually calibrating with a weight.
19.03	Describe the pharmacist checks for the measurement of each ingredient		As printed on the PK Compounding Log
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	Yes	

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		Finding	Notes
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	Yes	
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	See Doc 04
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Compliant	
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. Photograph and describe if found. Request copies of the invoices for products with questionable labels.	Compliant	

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		Finding	Notes
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	N/A	No animal compounding.
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	N/A	All APIs are received with an expiration date.
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	N/A	All APIs are received with an expiration date.
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	Compliant	One year or the actual expiration date if sooner.
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	Purified
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	N/A	No dietary or nutritional compounding.
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	

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		Finding	Notes
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.	N/A	No animal compounding.
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	N/A	
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Compliant	Compounder's International Analytical Laboratory for most extended BUD creams.
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	Compliant	See Doc 05

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		Finding	Notes
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Compliant	Except for the preparations with extended BUD documentation.
	Environment		
	Total Non-Compliant (Includes Unknowns)	**0**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	Per technician
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Compliant	Double HEPA filtered BSC. BSCs are not vented to the outside.
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	N/A	
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	Compliant	Located in a negative pressure room.

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		Finding	Notes
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*	Compliant	
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	Temperature at time of inspection was 69.00 degrees F.
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	Alarms are set
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.	Compliant	35.35% at time of inspection. Alert is set for above 60%.
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	

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		Finding	Notes
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	Compliant	
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	

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		Finding	Notes
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	N/A	No personnel from outside agencies.
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. Describe procedure used.	Compliant	Daily documented manual calibration and annually by an outside firm.
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Compliant	
58.01	Hood filters are checked regularly and replaced when necessary.	Compliant	
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*	Compliant	
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	

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		Finding	Notes
Documentation			
	Total Non-Compliant (Includes Unknowns)	**1**	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Compliant	
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	
61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	Located within the document
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Non-Compliant	No order of mixing
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Compliant	
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	Compliant	
61.12	Description of the finished preparation	Compliant	
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	

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Nonsterile Compounding Inspection

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Facility Name: Women's International Pharmacy Inc
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		Finding	Notes
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Compliant	
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	Compliant	Maintained electronically
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	

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		Finding	Notes
Compounding Procedures			
	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Compliant	
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	Compliant	
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	

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		Finding	Notes
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. Compounding MUST be observed. If compounding is not being performed at the time of survey mark as "Non-Compliant"*	Compliant	Observed a suppository, a cream and a capsule being compounded.
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization*		
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Compliant	
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	N/A	
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	Compliant	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	Compliant	

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		Finding	Notes
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	
80.03	Labeling contains storage and handling information.	Compliant	
80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	Batch should be dispensed in approximately 1 month.
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.	Compliant	

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		Finding	Notes
Patient Counseling and Communication			
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	Printed material and verbally
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Compliant	
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

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		Finding	Notes
	Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. *(NA if no sample)*		NA. No sample collected during this inspection.
	Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully gown and enter buffer room(s), indicate reason*		Facility mandated that this inspector change to scrubs and fully garb head to toe with no exposed skin before entering buffer room.
	General Operations Information		
1.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy*	No	Reviewed 6 patient profiles 4 had no allergies and 5 had no disease states/medical conditions, none of the 6 had prescriptions from other pharmacies or OTCs.
1.02	Are sterile compounded prescriptions picked up at the pharmacy?	Yes	
1.03	Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	Yes	
1.04	Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	
2.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	This pharmacy does not distribute any items per RPh Thorpe.
2.01	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?	N/A	
2.02	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?	N/A	
2.03	Is the pharmacy registered with the FDA as an Outsourcing Facility?	No	
2.04	Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided*	No	Belmar has a corporate sales force.
3.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?	N/A	
4.00	Which of the following sterile compounds are prepared?		

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		Finding	Notes
4.01	Allergen extracts	No	
4.02	Parenteral solutions	Yes	
4.03	Parenteral *suspensions*	Yes	
4.04	Preservative-free parenterals	No	
4.05	Ophthalmic preparations	No	
4.06	Oral or nasal *inhalation* preparations (not topical sprays)	No	
4.07	Baths and soaks for live organs and tissues	No	
4.08	Irrigations for wounds and body cavities	No	
4.09	Any other sterile preparations (implants, pellets, etc.). *Provide list*	No	
5.00	Does the pharmacy compound investigational drugs? *Provide list*	No	
6.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and source/percent compounded (if any)*	No	0%. Per RPh Thorpe
6.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	N/A	
6.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	N/A	
7.00	Does the pharmacy perform **low-risk** compounding? *Indicate percentage of low-risk sterile compounding*	No	0%
7.01	Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?	N/A	
7.02	If low risk, are the compounds located in segregated area are BUD 12 hours or less?	N/A	
7.03	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		

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		Finding	Notes
7.04	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *(List the types of testing performed (potency, sterility, stability, etc)*	N/A	
8.00	Does the pharmacy perform **medium-risk** compounding? *Indicate percentage of medium-risk sterile compounding*	No	0%
8.01	Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?	N/A	
8.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
8.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *(List the types of testing performed (potency, sterility, stability, etc)*	N/A	
9.00	Does the pharmacy perform **high-risk** compounding? *Indicate percentage of high-risk sterile compounding.*	Yes	100%
9.01	Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?	No	Some sterile preparations have extended BUDs
9.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		See Doc 06
9.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *(List the types of testing performed (potency, sterility, stability, etc)*	Yes	ARL conducts sterility, potency, endotoxin and particle testing.
10.00	Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?	No	
11.00	Does the pharmacy perform compounding for **immediate use?** *Indicate percentage of immediate-use sterile compounding*	No	0%
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding* *NIOSH list of hazardous drugs including chemotherapy, hormones, etc.*	Yes	60%. Mostly testosterone.
12.01	Does pharmacy have a plan to comply with USP Chapter <800> by the implementation date? *Describe plan.*	Yes	RPh Thorpe considers the pharmacy 800 compliant.
12.02	Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH?	Yes	

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		Finding	Notes
12.03	Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?	Unknown	Hazardous waste is disposed of in the regular trash.
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format*	Yes	Printed copies are located on wall outside of prescription department door and electronically on each laptop.
14.00	Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe*	No	Per RPh Thorpe
15.00	Does the pharmacy compound using any Federally **controlled substances I-V**? *Indicate controlled substances used and percentage of controlled substance sterile compounding*	Yes	Testosterone is the only controlled substance used in sterile compounding. Pharmacy has just begun sterile compounding and does not have a percentage at the present time.
16.00	**APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, indicate the source of API.*	Yes	Biopeptek, WilliowBirch, and PharmaSource Direct
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	Primary source verification by both the pharmacy and corporate.
16.03	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding?	Yes	In PK software
17.00	Does the pharmacy use scales/balances for sterile compounding?	Yes	
17.01	If so, what type of scale/balanced is used? *List manufacturer and model number.*		2 Ohaus Explorers EX225/AD and 4 Ohaus EX423
17.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*	Yes	Daily manually calibrated and calibrated by annually Analytic and Precision.
18.00	Does the pharmacy have a **lyophilizer**?	No	
18.01	Where is the lyophilizer located? *Indicate location and ISO class of room*		

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		Finding	Notes
18.02	Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.		
18.03	Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?	N/A	
19.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in-house?*	Yes	Bubble point and viable and nonviable surface and air sampling.
20.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	Yes	ARL and Pharmetric for potency, sterility and endotoxin testing.
21.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include sterile compounding measures? *Note: If the facility indicates "yes", please ask each question below to verify.*	Yes	
21.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
21.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?	Yes	
21.03	Does the pharmacy continuous quality improvement program include viable environmental testing?	Yes	
21.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
21.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
21.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?	Yes	
21.07	Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)?	Yes	

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		Finding	Notes
21.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?	Yes	
21.09	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
21.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	Yes	
21.11	Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA.	Yes	
21.12	Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? Review QA trends	Yes	
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	
22.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
22.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products. NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.	Compliant	See Doc 07
22.02	USP- or NF-grade substances used, if available.	Compliant	

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		Finding	Notes
22.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Compliant	
22.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable status.*	Compliant	
22.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.	N/A	No animal compounding.
22.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
22.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.*	N/A	All APIs have an expiration date.
22.08	All APIs are labeled with the date they were received.	Compliant	
22.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	N/A	
22.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
23.00	There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	

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Sterile Compounding Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
24.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
25.00	For **animal compounding**, does the compounding meet the same standards as compounding for human patients?	N/A	No animal compounding.
25.01	The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	N/A	
25.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
25.03	The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
25.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
25.05	The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
26.00	If the pharmacy compounds **stock solutions** or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.	Compliant	
26.01	The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD.	Compliant	
26.02	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.	Compliant	

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		Finding	Notes
Environment			
	Total Non-Compliant (Includes Unknowns)	**1**	
27.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.	Compliant	
28.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.	N/A	No compounding with blood items.
28.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?	N/A	
29.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).	Compliant	
30.00	The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.	Compliant	
30.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.	Compliant	
30.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.	Compliant	
31.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	Compliant	
32.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.*	Compliant	
33.00	The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams between the tiles and where they meet the walls shall be caulked and sealed.*	Compliant	
34.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	Compliant	
35.00	The clean/buffer room or anteroom does not have dust collecting overhangs.	Compliant	

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		Finding	Notes
36.00	The exposed surfaces of:		
36.01	PEC are free of dirt, rust, chips and particulate matter.	Compliant	
36.02	Light fixtures are smooth, mounted flush, and sealed.	Compliant	
37.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).	Compliant	
38.00	There is no sink or drain in the clean/buffer room.	Compliant	
39.00	Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.	Compliant	
39.01	If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)*	N/A	
40.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment.	Compliant	
41.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.	Compliant	
42.00	If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use.	N/A	No particle generating equipment is located in any of the ante or buffer rooms.
43.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	Compliant	
44.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.	Compliant	

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		Finding	Notes
44.01	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	Compliant	
45.00	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.	Compliant	
45.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.	Compliant	
45.02	Clean/buffer room is at least 0.02" wc positive pressure to Anteroom.	Compliant	
45.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.	Compliant	
45.04	Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device. *View logs*	Compliant	Continuously monitored and pharmacist are alerted via email.
45.05	Written plan in place to detect and react to pressure differentials outside of limits.	Compliant	
46.00	If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.	N/A	Anteroom and buffer rooms are fully enclosed.
46.01	The air flow is at least 40 feet per minute across the entire opening.	N/A	
46.02	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*	N/A	
46.03	Written plan in place to detect and react to air flow measurements outside of limits	N/A	
46.04	This area is used only for low- and medium-risk compounding (**HD and high-risk not allowed**).	N/A	
47.00	**Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions.	Compliant	
47.01	Temperature in the **compounding area** is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements. *Temperature records are maintained.*	Compliant	65.85, 64.99 and 65.68 degrees F at time of inspection.

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Facility Name: Women's International Pharmacy Inc
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		Finding	Notes
47.02	If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.*	Compliant	
47.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.04	Temperature monitoring in the **drug storage area** is performed at least once daily and documented. *Temperature records are maintained.*	Compliant	
47.05	Temperature in the **refrigerator or cooler** is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.	Compliant	Temperature at time of inspection was 3.93 degrees C.
47.06	Temperature monitoring in the **refrigerator** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained.*	Compliant	
47.07	Temperature in the **freezer** is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.	Compliant	Alarms are set for a low of minus 25 and a high of minus 10 degrees C. Minus 16.69 degrees C at time of inspection.
47.08	Temperature monitoring in the **freezer** is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained.*	Compliant	
47.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.	Compliant	
48.00	**Humidity:** If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. (*Generally recommended range is 35-60% for performing sterile compounding.*)	Unknown	17.10%, 23.38% and 26.31% at time of inspection.
48.01	If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	

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		Finding	Notes
48.02	If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
48.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).	Compliant	
49.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.	Compliant	
50.00	When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces	Compliant	ISO 5 blowers run 24/7.
51.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	Compliant	Interlocking.
52.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	Compliant	Interlocking.
53.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room**: BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.	N/A	All PECs are located in an ISO 7 area.
53.01	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage*	N/A	
53.02	All garbing requirements are adhered to.	N/A	
53.03	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	
53.04	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?	N/A	
53.05	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).	N/A	

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		Finding	Notes
54.00	**If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.	N/A	All PECs are located in an ISO 7 area.
54.01	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.	N/A	
54.02	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	
54.03	The sink is separated from the immediate area of the CAI or CACI (not adjacent).	N/A	
54.04	For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.	N/A	
	Cleaning and Disinfection		
	Total Non-Compliant (Includes Unknowns)	**0**	
55.00	Are all personnel performing cleaning appropriately garbed?	Compliant	
56.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	Compliant	
57.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area?	Compliant	
58.00	Are reusable tools appropriately labeled to prevent them from being used inappropriately?	Compliant	
59.00	For cleaning and sanitizing agents that are not "ready-to -use" formulations, are there formulas and instructions for mixing or diluting the agents prior to use and is the preparation documented?	Compliant	
60.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present*	Compliant	

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		Finding	Notes
61.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	Compliant	
62.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	Compliant	
62.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*	Compliant	Peridox RTU and Steriperox RTU. Decon-Spor Plus and TexQ as backups.
63.00	Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?	Compliant	
64.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	Compliant	
65.00	Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding.	Compliant	
66.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?	N/A	No fatigue mats.
67.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?	Compliant	
68.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* *Check inside bins and shelving for dust if you are unsure.*	Compliant	
69.00	Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?	Compliant	

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		Finding	Notes
Training *-Verify records of all compounding personnel (up to 10).*			
	Total Non-Compliant (Includes Unknowns)	**1**	
70.00	There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, cleaning/disinfection/spills, garbing/gowning/hand hygiene, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding.* List number of personnel training files viewed.	Compliant	2 pharmacists and 3 technicians. The pharmacy has been conducting sterile compounding less than six months.
70.01	All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.	Compliant	
70.02	All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.	Compliant	
71.00	All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.*	Compliant	
72.00	There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.	Compliant	
73.00	There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. *Documentation needs to include training on operation, and troubleshooting*	Compliant	
74.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. View documentation.	N/A	No relief personnel.

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		Finding	Notes
75.00	There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs when applicable. *Indicate frequency, if testing more than annually.*	Compliant	At least annually
76.00	There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*	Compliant	At least annually
77.00	There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency, if testing more than annually.*	Compliant	Gowning and gloving is evaluated quarterly and gloved finger tip testing with each batch.
78.00	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than annually.*	N/A	Only high risk.
79.00	There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than annually.*	Non-Compliant	Quarterly. PIC Mogen has not completed her current six month media fill.
80.00	The media-fill testing procedures include:		
80.01	Media selection (including obtaining COAs or growth promotion certificates from suppliers)	Compliant	
80.02	Fill Volume	Compliant	

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		Finding	Notes
80.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.)	Compliant	
80.04	Inspection of filled units	Compliant	
80.05	Documentation	Compliant	
80.06	Interpretation of results	Compliant	
80.07	Action levels set with the corrective actions required	Compliant	In a SOP
81.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results.* Indicate frequency, if testing more than every 6 months	Compliant	Gowning and gloving is evaluated quarterly and gloved finger tip testing is performed with each batch.
82.00	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding.* Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.	Compliant	Quarterly
83.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.	Compliant	
83.01	Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.	Compliant	Belmar has an in-house lab for identification if any growth.
83.02	There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.	Compliant	

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Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
Garbing			
	Total Non-Compliant (Includes Unknowns)	**0**	
84.00	Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	Compliant	
85.00	Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas.	Compliant	
86.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.	Compliant	
87.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	Compliant	
88.00	Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).	Compliant	Sterile compounding was demonstrated by Ms Bailey.
89.00	Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a method available to assure that all hair is covered.*	Compliant	Ms Bailey donned sterile coverall to include head hood and googles. There was no exposed skin.
90.00	Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	Compliant	
91.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	Compliant	
92.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	Compliant	
93.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*	Compliant	Avagard

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		Finding	Notes
94.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	Compliant	
95.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	Compliant	
96.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example)	Compliant	
	Environmental Monitoring		
	Total Non-Compliant (Includes Unknowns)	**0**	
97.00	The most recent PEC and room certification report is available.	Compliant	CEM conducts the certification.
97.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	Compliant	Hazardous-9/5/23 Non-hazardous 5/18/23
97.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	Compliant	
97.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated or altered, or major service to the facility is performed. *If non-compliant, record the date of the previous certification.*	Compliant	Only one certification for the non-hazardous and hazardous areas since this is a newly constructed sterile compounding area.
97.04	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	Compliant	
97.05	If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.	Compliant	

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		Finding	Notes
97.06	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	Compliant	
98.00	The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).	Compliant	
98.01	The equipment used had not exceeded its calibration date at the time of certification.	Compliant	
99.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.	Compliant	
99.01	ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*	Compliant	
99.02	ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*	Compliant	
99.03	ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*	Compliant	
99.04	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.	Compliant	
100.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.	Compliant	
100.01	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate **unidirectional** airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	Compliant	

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		Finding	Notes
100.02	Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs	Compliant	
100.03	Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.	Compliant	
101.00	Differential air pressure between rooms was measured.	Compliant	
101.01	The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.	Compliant	
101.02	The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.	Compliant	
102.00	Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.	N/A	
102.01	Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*	N/A	
103.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.	Compliant	
103.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).	Compliant	
103.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).	Compliant	
103.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).	Compliant	
104.00	HEPA filter tests were performed.	Compliant	

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		Finding	Notes
104.01	All room HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
104.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
105.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.	Compliant	
106.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency*	Compliant	
106.01	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*	Compliant	
106.02	Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*	Compliant	
106.03	Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected? *Note: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.*	Compliant	
106.04	Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	Compliant	
106.05	Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification Air Sample Surface Sample ISO Class 5 >1 CFU/m3 >3 CFU/plate ISO Class 7 >10 CFU/m3 >5 CFU/plate ISO Class 8 >100 CFU/m3 >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.*	Compliant	

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		Finding	Notes
106.06	CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	Compliant	
106.07	If the number of CFUs detected **in the rooms** exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.08	If the number of CFUs detected **in the PECs** exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.09	If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation(e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
107.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. Indicate the sample weight used to verify gravimetric and frequency of verifications.	Compliant	Weekly air and surface sampling. If any growth the culture is sent to Belmar.
	Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
108.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	Compliant	
109.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.	Compliant	New gauges. Will be calibrated annually.

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		Finding	Notes
110.00	All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented	Compliant	AZ Air Balance Company
111.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.	Compliant	
111.01	There is documentation of the ACD tubing being changed or discarded every 24 hours	Compliant	With each compounding
111.02	The ACD is used when performing media fill testing.	Compliant	
	Compounding Procedures		
	Total Non-Compliant (Includes Unknowns)	**0**	
112.00	Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).	Compliant	
113.00	Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	Compliant	
114.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.	Compliant	
115.00	Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	Compliant	
116.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA).* Compounding MUST be observed - if compounding is not being performed at the time of survey mark item as "Non-Compliant"	Compliant	Sterile compounding was demonstrated by Ms Bailey.

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		Finding	Notes
116.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization.*		
117.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	Compliant	
118.00	All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.	N/A	All sterile compounding is high risk starting with APIs.
119.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*	N/A	
120.00	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.*	N/A	
121.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.	N/A	
122.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions. List records reviewed.*	Compliant	Sermorelin Acetate 2mg/ml and Gonadorelin Acetate 0.2mg/ml
122.01	Official or assigned name, strength and dosage of the preparation	Compliant	
122.02	Names, lot numbers and expiration dates of all components	Compliant	
122.03	Total quantity or number of units compounded	Compliant	
122.04	Person compounding the preparation	Compliant	
122.05	Person performing the quality control procedures	Compliant	
122.06	Person who approved the preparation	Compliant	

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		Finding	Notes
122.07	Date of compounding	Compliant	
122.08	Assigned internal identification number or prescription number	Compliant	
122.09	Assigned BUD and reference if extended beyond USP guidelines	Compliant	
122.10	Duplicate label	Compliant	
122.11	Sterilization method (if applicable)	Compliant	
122.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable	Compliant	
123.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is* ***recommended*** *to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	Compliant	
124.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
125.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use.	Compliant	
126.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos if possible.* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**	Compliant	

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		Finding	Notes
127.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen	Compliant	
128.00	If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation used in the documentation including concentration of all active ingredients, excipients, etc.*	Compliant	
129.00	If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below.* List the products reviewed	Compliant	See Doc06
130.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.	Compliant	
131.00	**Filter sterilization** in an ISO 5 environment and documentation includes:		
131.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.	Compliant	
131.02	The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling on the filter does not indicate "research only" or "laboratory only", for example).	Compliant	
131.03	Is the appropriate capacity filter being used for the volume being filtered.	Compliant	
131.04	Filtering is completed rapidly without filter replacement.	Compliant	

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		Finding	Notes
131.05	Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.	Compliant	
132.00	**Steam sterilization** documentation includes:		No steam sterilization
132.01	The autoclave has been verified for the exposure time and mass of the items to be sterilized	N/A	
132.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices	N/A	
132.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization	N/A	
132.04	That the CSP will not be adversely affected by the steam and heat	N/A	
132.05	The description of steam sterilization includes conditions and duration for specific CSPs	N/A	
132.06	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices.	N/A	
133.00	**Dry heat sterilization** documentation includes:		No dry heat sterilization
133.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture	N/A	
133.02	Sufficient space is left between materials to allow for air circulation	N/A	
133.03	The description of dry heat sterilization includes conditions and duration for specific CSPs	N/A	
133.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices.	N/A	
133.05	Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period.	N/A	
134.00	**Depyrogenation by dry heat** documentation includes:		

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Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
134.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes	Compliant	
134.02	The description of the cycle and duration for specific load items	Compliant	
134.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)	Compliant	
134.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins	Compliant	
135.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method*	N/A	
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
136.00	Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?	Compliant	
137.00	Are there checks for container, closure integrity and any other apparent visual defects?	Compliant	
138.00	Is compounding accuracy documented by verification of steps?	Compliant	
139.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	Compliant	
140.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	Compliant	
141.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below describe*		ARL
141.01	Sterility testing includes both bacterial and fungal testing.	Compliant	
141.02	Sterility testing is performed for all CSPs that have extended BUDS.	Compliant	

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Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
141.03	Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers	Compliant	
141.04	Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized	N/A	Filter sterilized immediately after compounding.
141.05	The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Not more than 100, test 10% or four units, whichever is greater 2. More than 100 but more than 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Not more than 200 containers, test 5% or 2 containers, whichever is greater 2. More than 200, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.	Compliant	
141.06	For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken*	N/A	No failed testing.
141.07	If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken*	N/A	No dispensing prior to sterility testing.
142.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe*		
142.01	Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials)	Compliant	
142.02	High-risk CSPs prepared in multiple dose vials for administration to multiple patients	Compliant	
142.03	High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized	N/A	Filter sterilized immediately after compounding.
142.04	For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken*	N/A	No failed testing.

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Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Women's International Pharmacy Inc
e-Profile ID: 758539
Inspection Date: 10/16/2023 & 10/19/2023

		Finding	Notes
Patient Counseling and Communication			
	Total Non-Compliant (Includes Unknowns)	**0**	
143.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Compliant	Printed material and verbally.
144.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?	Compliant	
145.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
146.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.	Compliant	

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review
EMT	Emergency medical technician

EPA	Environmental Protection Agency
FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement
QRE	Quality Related Event
RAM	Radioactive Material

RCRA	Resource Conservation and Recovery Act
REMS	Risk evaluation mitigation strategy
RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.
Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor

List of Attachments

Attachment Name	Description
Doc01_GP_15.00_WomensInternationalPharmacyInc_Youngtown_AZ	List of Licenses for Women's International Pharmacy
Doc02_GP_19.00_WomensInternationalPharmacyInc_Youngtown_AZ	List of Licenses for Women's International Pharmacy
Doc03_NS_19.01_WomensInternationalPharmacyInc_Youngtown_AZ	Non-Sterile Compounding Scales
Doc04_NS_21.01_WomensInternationalPharmacyInc_Youngtown_AZ	COAs for Medisca, Letco, Spectrum and RLC Labs
Doc05_NS_29.01_WomensInternationalPharmacyInc_Youngtown_AZ	List of Non-Sterile Compounds with Extended BUDs
Doc06_ST9.02_WomensInternationalPharmacyInc_Youngtown_AZ	List of Sterile Compounds with Extended BUDs
Doc07_ST22.01_WomensInternationalPharmacyInc_Youngtown_AZ	Photo of Tablet Press and Compounding Records
Doc08_CPD_WomensInternationalPharmacyInc_Youngtown_AZ	COAs for Biopeptek, WilliowBirch, PharmaSource Direct

States in which Women's International Pharmacy, Inc. in Youngtown, AZ is licensed

State	License Type	License Number	Expiration
Alabama	Non-Resident Pharmacy	113354	12/31/2024
Alabama	Controlled Substance Registration	113354	12/31/2024
Alaska	Out-Of-State Pharmacy	171884	06/30/2024
Arizona	Resident Pharmacy	Y008610	10/31/2024
Arkansas	Retail Pharmacy License	OS02132	12/31/2023
California	Nonresident Pharmacy	NRP 2520	03/01/2024
Colorado	Prescription Drug Outlet Out of State	OSP 0005432	10/31/2024
Connecticut	Nonresident Pharmacy	PCN.000058	08/31/2024
Delaware	Non Resident Pharmacy	AS-0012610	09/30/2024
Delaware	Controlled Substance Registration	PH-0024699	06/30/2025
Florida	Pharmacy License	PH 24499	02/28/2025
Georgia	Non-resident Pharmacy	PHNR002083	06/30/2025
Hawaii	Miscellaneous Permit	PMP-1803	12/31/2023
Hawaii NED	Controlled Substance	E15319	05/31/2024
Idaho	Out of State Mail Service Pharmacy Registration	61712MS	12/31/2023
Illinois	Licensed Pharmacy	054.021906	03/31/2024
Illinois	Licensed Controlled Substance	320.013503	03/31/2024
Indiana	Non-resident Pharmacy	64003156A	12/31/2023
Iowa	Non-resident Pharmacy	3893	12/31/2023
Iowa CS	Controlled Substance	1108324	12/31/2023
Kansas	Non-resident Pharmacy	22-114578	06/30/2024
Kentucky	Non-resident Pharmacy	AZ2763	06/30/2024
Louisiana	Non-resident Pharmacy	PHY.008374-NR	12/31/2023
Maine	Mail Order Pharmacy	MO40002965	12/31/2023
Maryland	Non-resident Pharmacy	P08406	05/31/2024
Maryland	Controlled Substance Registration	4105709	12/31/2023
Michigan	Non-resident + CS	5301008367	03/15/2024
Michigan	Controlled Substance Registration	5315025661	03/15/2024
Minnesota	Non-resident Pharmacy	266376	06/30/2024
Mississippi	Non-resident Pharmacy	06097/7.1	12/31/2023
Mississippi	Controlled Substance Registration	CS-06097	12/31/2023
Mississippi	Compounding Certificate	CC-18280/7.1	12/31/2023
Missouri	Non-resident Pharmacy	2021012115	10/31/2025
Montana	Non-resident Pharmacy	PHA-MOP-LIC-79407	11/30/2024
Nebraska	Non-resident Pharmacy	611	07/01/2024
Nevada	Non-resident Pharmacy	PH01886	10/31/2024
New Hampshire	Non-resident Pharmacy	NR2144	12/31/2024
New Jersey	Non-resident Pharmacy	28RO00048400	06/30/2024
New Mexico	Non-resident Pharmacy	PH00005169	12/31/2024
New Mexico	Controlled Substance Registration	CS00229780	05/31/2024
New York	Non-resident Pharmacy	032593	01/31/2026

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States in which Women's International Pharmacy, Inc. in Youngtown, AZ is licensed

North Carolina	Non-resident Pharmacy	14644	12/31/2023
North Dakota	Non-resident Pharmacy	Phar1816	06/30/2024
Ohio	Non-resident Pharmacy	021422250	03/31/2025
Oklahoma	Non-resident Pharmacy	99-8926	03/31/2024
Oklahoma	Controlled Substance Registration	35558	10/31/2024
Oregon	Non-resident Pharmacy	RP-0002133	03/31/2024
Oregon	Controlled Substance Registration	RP-0002133-CS	03/31/2024
Pennsylvania	Non-resident Pharmacy	NP000124	08/31/2025
Rhode Island	Non-resident Pharmacy	PHN12080	09/30/2024
Rhode Island	Controlled Substance Registration	CPHN12080	09/30/2024
South Carolina	Non-resident Pharmacy	20054	06/30/2024
South Carolina	Controlled Substance Registration	13-20054	04/01/2024
South Dakota	Non-resident Pharmacy	400-0400	06/30/2024
Tennessee	Non-resident Pharmacy	0000004506	02/28/2025
Texas	Non-resident Pharmacy	33882	07/31/2025
Utah	Non-resident Pharmacy	12160567-1708	09/30/2025
Utah	Controlled Substance Registration	12160567-8913	09/30/2025
Vermont	Non-resident Pharmacy	036.0134534	07/31/2025
Virginia	Non-resident Pharmacy	0214000785	12/31/2023
Washington	Non-resident Pharmacy	PHNR.FO.60153995	05/31/2024
Washington DC	Non-resident Pharmacy	NRX2101841	05/31/2025
Washington DC	Controlled Substance Registration	NCP2100017	05/31/2025
West Virginia	Non-resident Pharmacy and Controlled Substance	MD0561829	06/30/2025
Wisconsin	Non-resident Pharmacy	2567-43	05/31/2024
Wyoming	Non-resident Pharmacy	NR-51965	06/30/2024
Wyoming	Controlled Substance Registration	CSB01004	06/30/2024
DEA	Controlled Substance Registration	FW0066856	05/31/2024

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INSPECTION REPORT

Pharmacy | Hospital Pharmacy | Clinic | Exempt Hospital | Wholesaler | Hypodermic

Date: 9/27/2023 Inspector: Lyle Matthews

Firm: WOMENS INTERNATIONAL PHARMACY INC Phone: (800) 699-8143

Address: 12012 N 111TH AVE City: YOUNGTOWN Zip: 85363

Ownership: CORPORATION

Permit #: NSC000000 NRP2520 Permit Exp: DEA#: FW0066856 DEA Exp: 5/31/2024

Date of Self Assessment Form: 9/27/2023 Other Permit #: NRP2520 Date of DEA Inventory: 5/1/2023

Hours M-F: 0800 - 1800 MST Hours Saturday 0900 - 1200 Hours Sunday: CLOSED

PIC **SUSAN MOGEN** OUT Administrator

RPH Consultant

Staff RPH Name:	License #:
FEE ONG JR	OUT
HERSHIL PAREKH	OUT
ATHENA MARMENTER	OUT
KARI BERTHOLD	OUT
IMELDA HANAFI	OUT
JULIE LOUNSBERY	OUT
JESSE MOGEN	OUT
MATTHEW THORPE	OUT
ELMER MARES-MORALES	OUT
ROBERT CARUSO II	OUT
KATIE LUND	OUT

Staff Name:	License #:
ALEXIS MOYER	OUT
ANGEL PEREZ	CLERK
ANGELA PHILLIPS	OUT
ARIELLE BAILEY	OUT
BRANDON SWIFT	DRIVER
CHERYL GRABO	OUT
DANA LARSON	MANAGER
ELIZABETH DIAZ	OUT
GIANNA LENTZ	OUT
JAMES TUDEHOPE	OUT
JENNIFER MONDORO	OUT
JENNIFER ROSEBERRY	OUT
JERRILYN SHABI	OUT
JOEL TODD	CLERK
KELSEY GATTO	OUT
LEEANN MORRISON	OUT
LISA SNACHEZ	OUT
LUCY ARIZMENDEZ	OUT
MAGDALENA DEE	OUT
MARICELA GUTIERREZ	OUT
MEGAN NIXON-SANDBERG	OUT
MICHELE CORRIGAN	OUT
MIGUEL ORDAZ	OUT
NICOL CARPENTER	OUT

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SELENA FERNANDEZ	OUT
TAMMI NAGEL	MANAGER
TIFFANY WINTERICH	OUT
TRINIDAD SWIFT	OUT
VALENTINA SHABI	OUT
WILLIAM GUERENA	CLERK

Inspector Remarks:

Performing on-site new non-resident sterile compounding inspection at Women's International Pharmacy, Inc in Youngtown, AZ. PIC Susan (Sue) Mogen, Arizona facility Quality Manager Dana Larson, and Belmar Pharma Solutions Vice President of Quality Anne Szilagyi are present and assisting in the inspection.

PIC Mogen's Contact information is: E-mail: smogen@womensinternational.com Phone: 800-699-8143

Women's International Pharmacy was founded in 1985. The Arizona facility is one of two Women's International Pharmacies licensed with the State of California. The other is in Madison, Wisconsin (NRP2519), which was originally licensed with CA in 1991. The Arizona location has been licensed as a CA Non-Resident Pharmacy (NRP) since September 2003 with the current NRP2520 issued in March 2021. Women's International Pharmacy was acquired by Belmar Pharma Solutions (BPS) and became part of the BPS organization in March 2021.

Women's International Pharmacy specializes in providing primarily compounded bioidentical hormone replacement therapies to patients in all 50 states, including California, through non-sterile compounding up to this point. The facility has now applied with the CA Board of Pharmacy to add a non-resident sterile compounding license to be able to provide sterile products in addition to their current offerings. They are also in the process of applying to other states for their sterile compounding licenses. Per Quality V.P Szilagyi, part of the strategy to obtain sterile compounding licenses is to have some company redundancy for sterile compounding as Belmar has one other company owned 503A facility in Florida.

The facility has 21,700 square feet. Aside from the compounding areas, there is an entry/reception area, a conference room, staff break room, warehouse area, customer service area with work stations, etc. There are currently 42 employees with three full time employees working in the quality department. PIC Mogen states they fill approximately 300 - 500 prescriptions per day.

An entire tour of the facility was taken during inspection. The compounding area is

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completely new. An entire construction project was commenced in September 2021 and was recently completed. There are brand new rooms and defined areas for each step of the sterile and non-sterile compounding process. These include two separate sterile compounding suites for HD and non-HD sterile compounding.

Other Inspections:

- NABP inspection was completed approximately two years ago and per PIC Mogen they are expected to inspect again soon.
- Arizona Board of Pharmacy inspected the new construction for the compounding area in March 2023.

LSC Inspection:

The new compounding area is a state of the art extensive modular suite with a number of different areas including:

- Staff locker rooms
- Sterile Packaging Room
- Sterile glass room
- Dish washing room
- Storage areas
- Locked chemical storage rooms
- Decontamination room

Compounding Area:

- Flooring: Sheet vinyl throughout
- Walls: Clean and washable
- Sink: Stainless steel in ante rooms
- Emergency Eye Wash Station: Outside classified areas. Additional eye wash bottles inside compounding areas.
- Air Pressure Monitoring: Electronic and continuous

Positive Pressure Ante Room: Room 110A

- ISO7
- Air Exchanges Per Hour: 53.6
- Air Pressures: +0.032
- Stainless steel sink
- Line of Demarcation embedded in sheet vinyl
- Mirror
- Stainless steel benches

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- Pass thru window

Positive Pressure Buffer Zone #1: Room 110B
- ISO7
- Air Exchanges Per Hour: 33.
- Air Pressures: +0.035

Powder Hoods in non-HD sterile prep room.
- AirClean Systems Model AC775C, Serial AC775C-1613
- AirClean Systems Model AC775C, Serial AC775C-1614
- AirClean Systems Model AC775C, Serial AC775C-1615

Positive Pressure Buffer Zone #2: Room 110C
- ISO7
- Air Exchanges Per Hour: 30.2
- Air Pressures: +0.036
- Stainless steel carts
- Repeater pumps
- Pass thru window
- Laminar Flow Hood/Cabinet:
  - ISO5 Germfree Model BZ-6SSRX, Serial 6S-15-BH-20930
  - ISO5 Germfree Model BZ-6SSRX, Serial 6S-15-BH-20931
  - ISO5 Germfree Model BZ-6SSRX, Serial 6S-15-BH-20932
  - ISO5 Germfree Model BZ-6SSRX, Serial 6S-15-BH-20933

Non-Hazardous Drugs Prepared:
- Currently:
  - Primarily non-sterile hormone replacement products
    - Creams
    - Ointments
    - Capsules
    - Troches
    - Suppositories
- When sterile compounding license received:
  - Sterile compounds
    - Testosterone Injections
    - Trimix - different strengths
    - Phenylephrine 1mg/ml

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Negative Pressure Ante Room: Room 115A
- ISO7
- Air Exchanges Per Hour: 66.2
- Air Pressures: -0.022 (+0.064 to unclassified room)
- Stainless steel sink
- Stainless steel benches
- Stainless steel carts
- Stainless steel pass-thru
- HEPA filters in ceiling

Negative Pressure Buffer Zone #1: Room 115B
- ISO7
- Air Exchanges Per Hour: 54.0
- Air Pressures - 0.026

Negative Pressure Buffer Zone #2: Room 115C
- ISO7
- Air Exchanges Per Hour: 38.4
- Air Pressures

Class II Biological Safety Cabinets:
- There are seven total BSC's
  - Three are in prep area
  - Four are in the HD Buffer Zone
- NuAire, Model NU-543-600, Serial 209586112921 (BSC1)
- NuAire, Model NU-543-600, Serial 210723011022 (BSC2)
- NuAire, Model NU-543-600, Serial 210118120821 (BSC3)
- NuAire, Model NU-543-600, Serial 210730011022 (BSC4)
- NuAire, Model NU-543-600, Serial 209582112921 (BSC5)
- NuAire, Model NU-543-600, Serial 209627120221 (BSC6)
- NuAire, Model NU-543-600, Serial 209616120121 (BSC7)

Hazardous Drugs Prepared:
- Sterile HD compounding will primarily be Testosterone

CSTD System: N/A

Certification: :Controlled Environment Management, LLC.
- Testing performed between Feb and May 2023 for non-HD area and in Aug. 2023 for

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Sacramento, CA 95833
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Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Compounding Log:
- Several batch records reviewed
  - Estriol/Estradiol/Progesterone/DHEA 3.6/0.9/100/20 Lot # 09262023@131
- Batch records are produced in PK software
- Each batch record reviewed complied with assigned BUD from shortest date of ingredients used.

Controlled Substances:
- Diazepam suppositories
- Gabapentin topical
- Testosterone
- No schedule II controlled substances in inventory

Cleaning Documentation:
- Documentation recorded in Pestle system
- Cleaning will be performed by pharmacy staff only

Refrigerator/Freezer Logs:
- Recorded in Enteliweb system
- Data is sent to the Delta Control system
- If out of range, message is sent to facility staff

Security:
- Employee badge readers for access to all licensed areas
- Security cameras throughout facility
- Alarm system in place

Cleaning Agents:
- PREempt
- Peridox
- Deco-Spore
- Tex-Q
- Sterile IPA

Training:
- Fingertip testing every three months
- Media fill testing every three months
- Observational competencies

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INSPECTION REPORT

HD area
- Environmental Viable Sampling:
  - Passed during certification
- Air Exchanges:
  - Passed during certification
- HEPA Filtration:
  - HEPA filters in ceiling throughout classified area

Smoke Tests:
- Viewed with Quality Manager Larson during inspection

PPE/Garbing:
- All required PPE is available in all required locations of the facility
- Sterile gloves that meet ASTM D 678 requirements are available
- Bootie Butler system is utilized throughout the compounding area

BUD's:
- 180 days maximum currently for non-sterile products
- 60 days maximum for sterile products pending the new USP guidelines taking effect 11/1/23

Labeling:
- Reviewed several labels during tour of facility
  - Estriol/Estradiol/Progesterone/DHEA 3.6/0.9/100/20 Lot # 09262023@131
  - Progesterone 120mg/gm Cream Lot # LG1832718
- All required elements are on label.

Adverse Drug Reactions:
- Complaint process in place
- Information obtained on initial call
- Further investigated by compounding Manager and quality dept.
- Complaints are reviewed on a monthly basis

Master Formula:
- Reviewed for:
  - Estriol/Estradiol/Estrone 2.5/0.75/0.25 mg/gm Versapro ANH
  - Estriol/Estradiol/Estrone/Progesterone Olive 0.5/0.63/0.063/100mg Oil Capsule
  - Discussion to ensure clear directions on Master Formula for compounding personnel

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INSPECTION REPORT

- Garbing qualification
- Hand washing
- SOP training
- Aseptic technique
- Videos reviewed
- Etc.

- Quality Manager Larson under the supervision of V.P Szilagyi leads an extensive training program.

Pharmacist Review Process:
- Observed during inspection
- Pharmacist K.L. explained and demonstrated the pharmacist review process

Standard Operating Procedures:
- Corporate SOPs in place
- Facility/site specific SOPs in place
- Reviewed annually by PICs

Quality Assurance Program:
- Process Validation:
  - Process discussed with PIC
  - Will be implemented upon licensing of the sterile compounding area

Wholesaler:
- Amerisource Bergen
- Letco
- Medisca
- Willow Birch
- Spectrum
- Supriya Life Sciences Limited
- Biopeptek

Reverse Distributor:
- 123 Compliant Logistics

Shipping:
- Shipping to all 50 states
- Shipping area toured
- Shipping staff member Brandon was interviewed and observed for shipping process

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INSPECTION REPORT

- USPS, Fed Ex, UPS all utilized
- Shipping guidelines in place for temperature monitoring
- Shipping studies have been performed
- Temperature indicators included in every shipment requiring temperature monitoring.
- Refrigerated products shipped in insulated containers with ice packs and a temperature monitor

Education During Inspection:

- Ensure all API used for sterile compounding meets requirements for sterile products
- Security - Always ask for credentials from anyone representing themselves as being from a regulatory agency to ensure they are who they say they are.
- Security - Beware of scam callers representing themselves as being from a regulatory agency who threaten the status of your license and request money. No one from the CA Board of Pharmacy will call and request money.
- Security - Be aware of scam callers representing themselves as an agency that is asking for your wholesaler account number. There are scams that will order product under your account number, then call and say it was a mistake and want to pick up the order that is being delivered and steal the product.
- Date and label any open bottle, i.e. sterile IPA to indicate either date of opening and/or expiration date after opening and removal from sterile packaging.

If there have been changes in your policies and procedures in the last year, please provide an electronic copy of the new or changed polices and procedures. You may do this by sending a disk or CD to the Board or e-mail the new policies and procedures to: compounding.pharmacy@dca.ca.gov. Please use the pharmacy's California sterile compounding license number (LSC or NSC and five-digit number) on the disk, CD, or in the subject line of the e-mail to ensure proper identification. Please identify or list the changes to your procedures. Failure to identify or list the changes will hinder timely renewal.

Discussion:

Follow-up questions may be referred to Inspector Matthews at lyle.matthews@dca.ca.gov or to (909) 255-2973.

Licensee Remarks:

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Gavin Newsom, Governor

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) _____

Inspector (sign) _____

Owner(sign) _____

Inspector (print) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

Women's International Pharmacy Non-Sterile Scale list

Ohaus Scout	STX622
Ohaus Adventurer	AX124
Ohaus Scout	STX622
Ohaus Scout	STX622
Ohaus Scout	STX622
Ohaus Scout	STX622
Ohaus Scout	SPX621
Ohaus Scout	STC6201
Ohaus Explorer	EX224N
Ohaus Scout	STX6201
Ohaus Adventurer	AX8201N/E
Ohaus Explorer	EX423
Ohaus Scout	STX6201
Ohaus Scout	STX622
Ohaus Scout	STX622
Ohaus Adventurer	AX324
Ohaus Scout	STC6201
Ohaus Explorer	EX224N
Ohaus Scout	SPX621
Ohaus Scout	STX6201
Ohaus Explorer	EX224N
Ohaus Scout	STX6201
Ohaus Adventurer Pro	AV313
Ohaus Adventurer Pro	AV8101
Ohaus Scout	STX622
Ohaus Scout	STX622
Ohaus Scout	SPX621
Ohaus Scout	SPX621
Ohaus Explorer	EX423
Ohaus Scout	STX6201
Ohaus Scout	STX6201
Ohaus Explorer	EX224N

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 081023.2059.4.C212741625

Customer Name:	Customer #:	Address:	Bldg.: Main Lab
Women's International Pharmacy	2690	12012 N 111th Avenue	Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	EX423	C212741625	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 74.3 **F.°** **R.H.** 40 **%**
END TEMP 74.1 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023
Recall Date: 04/30/2024

420g / 0.001g — Capacity/Resolution
+/- 0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371F

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	200 g	400 g
1. Prior to Service	0.500 g	1.000 g	199.998 g	399.998 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	200.000 g	400.000 g
Corner Load	Weight Used: 100 g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

99.999 g	100.000 g	100.001 g	100.001 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00043 g	0.0009 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

Darta Larson — 08/10/2023 — **Customer**

Melinda Eigenmann — 08/10/2023 — **Authorized By**

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 081023.2059.4.C143832224

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: Main Lab
Women's International Pharmacy	2690	12012 N 111th Avenue	Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C143832224	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 69.5 **F.°** **R.H.** 49 **%**
END TEMP 69.1 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023 — 620g / 0.01g Capacity/Resolution

Recall Date: 08/31/2024 — +/- 0.05 g Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371F

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	3 g	10 g	300 g	600 g
1. Prior to Service	3 g	10 g	300.02 g	600.04 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	3 g	10 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200 g	Prior to Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	199.99 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0034 g	0.0067 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. **The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.**

Dana Larson — 08/10/2023
Customer

Melinda Eigenmann — 08/10/2023
Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 081023.2059.4.C143820262

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 11Th Avenue	Room: Non hazard
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX6201	C143820262	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 68.2 F.° R.H. 60 %
END TEMP 68.2 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023
Recall Date: 08/31/2024
6200g / 0.1g — Capacity/Resolution
+/- 0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371A

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	3000.0 g	5999.9 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	1 kg	Prior to Service	2 0.0 kg	3 0.0 kg
			1 0.0 kg	4 0.0 kg
Corner Load		After Service	2 0.0 kg	3 0.0 kg
			1 0.0 kg	4 0.0 kg

Repeatability Readings

1000.0 g	1000.0 g	1000.0 g	1000.0 g	1000.0 g	1000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE. DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

Dana Larson — Customer — 08/10/2023

Melinda Eigenmann — Authorized By — 08/10/2023

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 081023.2059.4.C212741626

IAS ACCREDITED
International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: Main Lab
Women's International Pharmacy	2690	12012 N 111th Avenue	Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	EX423	C212741626	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 69.3 **F.°** **R.H.** 53 **%**
END TEMP 69.3 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023
Recall Date: 08/31/2024

420g / 0.001g — Capacity/Resolution
+/- 0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711F

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	200 g	400 g
1. Prior to Service	0.500 g	1.000 g	200.002 g	400.004 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	200.000 g	400.000 g
Corner Load	Weight Used: 100 g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

99.999 g	99.999 g	100.000 g	100.000 g	99.998 g	99.999 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00043 g	0.0009 g

Comments:

1. **Prior to Service:**
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. **After Service:**
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT
Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

Dana Larson — 08/10/2023 — **Customer**

Melinda Eigenmann — 08/10/2023 — **Authorized By**

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 081023.2059.4.C143813742

IAS

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: Main Lab
Women's International Pharmacy	2690	12012 N 11th Avenue	Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX6201	C143813742	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 69.4 **F.° R.H.** 54 **%**
END TEMP 69.4 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023
Recall Date: 08/31/2024

6200g / 0.1g — Capacity/Resolution
+/- 0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371A

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	2999.5 g	5999.1 g
Tolerance Error	0.0 g	0.0 g	0.0 g	-0.9 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g
Corner Load	Weight Used: 1 kg	Prior to Service	2 0.0 kg	3 0.0 kg
			1 0.0 kg	4 0.0 kg
Corner Load		After Service	2 0.0 kg	3 0.0 kg
			1 0.0 kg	4 0.0 kg

Repeatability Readings

999.9 g	999.9 g	999.9 g	999.9 g	999.9 g	1000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.034 g	0.067 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

08/10/2023
Dana Larson — **Customer**

Melinda Eigenmann — **Authorized By** — 08/10/2023

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 0R1023.2059.4.C143832216

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: Main Lab
Women's International Pharmacy	2690	12012 N 111th Avenue	Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C143832216	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 68.2 **F.°** **R.H.** 55 **%**
END TEMP 68.2 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date:	08/10/2023	620g / 0.01g Capacity/Resolution
Recall Date:	08/31/2024	+/- 0.05 g Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371F

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	3 g	10 g	300 g	600 g
1. Prior to Service	3.00 g	10.00 g	299.99 g	600.00 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	3.00 g	10.00 g	300.00 g	600.00 g
Corner Load	Weight Used 200 g	Prior to Service	2 -0.01 g	3 -0.01 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 -0.01 g	3 -0.01 g
			1 0.00 g	4 0.00 g

Repeatability Readings

199.99 g	199.99 g	199.99 g	199.99 g	199.99 g	199.99 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0041 g	0.0081 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

Dana Larson 08/10/2023 — Customer

Melinda Eigenmann 08/10/2023 — Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 081023.2059.4.C14381387I

IAS — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main Lab
			Room:
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C14381387I	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 68.8 **F.°** **R.H.** 54 **%**
END TEMP 68.8 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/10/2023
Recall Date: 08/31/2024

620g / 0.01g — Capacity/Resolution
+/- 0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371F

Calibration Instructions: Internal Cal ☐ External Cal ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	3 g	10 g	300 g	600 g
1. Prior to Service	3.00 g	10.00 g	300.00 g	600.00 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	3.00 g	10.00 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200 g	Prior to Service	2 0.00 g	3 +0.01 g
			1 0.00 g	4 +0.01 g
Corner Load		After Service	2 0.00 g	3 +0.01 g
			1 0.00 g	4 +0.01 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0041 g	0.0081 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

08/10/2023
Dana Larson — **Customer**

Melinda Eigenmann — **Authorized By** — 08/10/2023

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Form # 1987 Rev. 8-20 — End of Report — Original: Vendor Copy: Customer

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 081023 2059 4 C219995006

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	EX224N	C219995006	

AZ RSR License #00 1840
AZ RSA License #014790
START TEMP 67.7 **F.°** **R.H.** 56 **%**
END TEMP ____ **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 08/11/2023
Recall Date: 08/11/2024

220g 0.000g — Capacity/Resolution
Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371F

Calibration Instructions: Internal Cal ☑ External Cal ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	100 g	200 g
1. Prior to Service	0.500 g	1.000 g	100.006 g	200.011 g
Tolerance Error	0.000 g	0.000 g	0.006 g	0.011 g
2. After Service	g	1.000 g	100.000 g	200.000 g

	Weight Used			
Corner Load	100 g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	100.000 g	100.000 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.000012 g	0.000023 g

Comments:
First time calibrating

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

08/11/2023
Dana Larson — Customer

Melinda Eigenmann — Authorized By 08/11/2023

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-B629782284

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Bldg.: Main Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	AX124	B629782284	24

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 72.9 **F.°** **R.H.** 23 **%**
END TEMP 72.9 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

120 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371J

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	60 g	120 g
1. Prior to Service	0.500 g	1.000 g	60.000 g	119.996 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	60.000 g	120.000 g

	Weight Used			
Corner Load	50g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

50.000 g	50.000 g	50.000 g	50.000 g	50.000 g	50.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00029 g	0.00058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT, Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-8030161062

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	AV8101	8030161062	4

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 69.7 **F.° R.H.** 22 **%**
END TEMP 69.7 **F.°**
TEMP GAUGE S/N 221227554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

8100 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	4000 g	8000 g
1. Prior to Service	50.0 g	100.0 g	3999.8 g	7999.4 g
Tolerance Error	0.0 g	0.0 g	0.0 g	-0.6 g
2. After Service	50.0 g	100.0 g	4000.0 g	8000.0 g

Corner Load	Weight Used	Prior to Service	2 0.0 g	3 +0.1 g
	2kg		1 0.0 g	4 +0.1 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

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04/21/2023 — Customer

04/21/2023 — Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C412787113

IAS ACCREDITED
International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX6201	C412787113	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 68.2 **F.°** **R.H.** 22 **%**
END TEMP 68.2 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371T

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	3000.0 g	5999.8 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

Corner Load	Weight Used	Prior to Service	2 0.0 g	3 0.0 g
	2kg		1 -0.2 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 -0.2 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.065 g	0.13 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

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04/21/2023
Customer

04/21/2023
Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C219995008

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	EX224N	C219995008	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 67.1 **F.° R.H.** 24 **%**
END TEMP 67.1 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

220 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371J

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	100 g	200 g
1. Prior to Service	0.500 g	1.000 g	100.000 g	200.000 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	100.000 g	200.000 g

	Weight Used			
Corner Load	100g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	100.000 g	100.000 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00029 g	0.00058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. **The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.**

04/21/2023 — **Customer**

04/21/2023 — **Authorized By**

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — ilac-MRA
International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-C143813731

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N. 116th Avenue	Bldg.: Main Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX6201	C143813731	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 66.6 **F.°** **R.H.** 24 **%**
END TEMP 66.6 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	2999.7 g	5999.0 g
Tolerance Error	0.0 g	0.0 g	0.0 g	-1.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 -0.2 g	3 0.0 g
			1 0.0 g	4 -0.2 g
Corner Load		After Service	2 -0.2 g	3 0.0 g
			1 0.0 g	4 +0.2 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.1 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.12 g	0.24 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a formal and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. **The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.**

04/21/2023 — Customer
04/21/2023 — Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-8032411031

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	AV313	8032411031	2

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 66.6 F.° R.H. 24 %
END TEMP 66.6 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

310 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371J

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	150 g	300 g
1. Prior to Service	0.500 g	1.000 g	150.000 g	300.000 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	150.000 g	300.000 g

	Weight Used			
Corner Load	100g	Prior to Service	2 0.000 g	3 +0.001 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 +0.001 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	100.000 g	100.000 g	100.001 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00044 g	0.00087 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

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Form # 1987 Rev. 8-20

End of Report

Original: Vendor Copy: Customer

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-B739739207

Customer Name:	Customer #:	Address:	Bldg.: Main
Women's International Pharmacy	2690	12012 N 11th Avenue	Room: Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	AX324	B739739207	B

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 66.6 **F.° R.H.** 24 **%**
END TEMP 66.6 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

320 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371J

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	150 g	300 g
1. Prior to Service	0.500 g	1.000 g	150.000 g	299.997 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	150.000 g	300.000 g

	Weight Used			
Corner Load	100g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	99.999 g	99.999 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00036 g	0.00073 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

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Form # 1987 Rev. 8-20

End of Report

Original: Vendor Copy: Customer

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143813891

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX6201	C143813891	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 66.2 **F.°** **R.H.** 24 **%**
END TEMP 66.2 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	3000.0 g	5999.8 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C219995007

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	EX224N	C219995007	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 66.4 **F.°** **R.H.** 24 **%**
END TEMP 66.4 **F.°**
TEMP GAUGE S/N 231727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

220 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123713

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	100 g	200 g
1. Prior to Service	0.500 g	1.000 g	100.000 g	199.998 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	100.000 g	200.000 g

	Weight Used			
Corner Load	100g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	100.000 g	100.000 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00029 g	0.00058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. **The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.**

04/21/2023
Customer

04/21/2023
Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED

ilac-MRA

International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-8342411416

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main
			Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	SPX621	8342411416	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.7 **F.°** **R.H.** 24 **%**
END TEMP 65.7 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.0 g	10.0 g	300.0 g	599.7 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	5.0 g	10.0 g	300.0 g	600.0 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

200.0 g	200.0 g	200.0 g	200.0 g	200.0 g	200.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT, Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023
Customer

04/21/2023
Authorized By

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(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C14382217

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 116th Avenue	Main
			Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C14382217	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.5 F.° R.H. 24 %
END TEMP 65.5 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	299.95 g	599.90 g
Tolerance Error	0.00 g	0.00 g	0.00 g	-0.10 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule: WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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Form # 1987 Rev. 8-20 — End of Report — Original: Vendor Copy: Customer

Analytical & Precision Balance Co., Inc.
The Weighing Solution
ANSI/ISO/IEC 17025 Accredited / GSA Contract Holder

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(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-C143820257

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 114th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX6201	C143820257	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.5 F.° **R.H.** 24 %
END TEMP 65.5 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	2999.6 g	5999.5 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	1999.9 g	1999.9 g	2000.0 g

*CORNER LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.036 g	0.073 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023
Customer

04/21/2023
Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C219995005

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	EX224N	C219995005	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.7 **F.°** **R.H.** 24 **%**
END TEMP 65.7 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

220 g / 0.001 g — Capacity/Resolution
+/-0.005 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371J

Calibration Instructions: Internal Cal. ☑ External Cal. ☐ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	0.5 g	1 g	100 g	200 g
1. Prior to Service	0.500 g	1.000 g	99.997 g	199.996 g
Tolerance Error	0.000 g	0.000 g	0.000 g	0.000 g
2. After Service	0.500 g	1.000 g	100.000 g	200.000 g

	Weight Used			
Corner Load	100g	Prior to Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g
Corner Load		After Service	2 0.000 g	3 0.000 g
			1 0.000 g	4 0.000 g

Repeatability Readings

100.000 g	100.000 g	100.000 g	100.000 g	100.000 g	100.000 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.00029 g	0.00058 g

Comments:

1. **Prior to Service:**
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. **After Service:**
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023
Customer

04/21/2023
Authorized By

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143820274

IAS ACCREDITED

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.:
Women's International Pharmacy	2690	12012 N 116th Avenue	Main
			Room: Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX6201	C143820274	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.9 **F.°** **R.H.** 24 **%**
END TEMP 65.9 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal ☐ External Cal ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	3000.0 g	6000.2 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 0.0 g	3 -0.1 g
			1 -0.1 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 +0.1 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2800.0 g	1999.9 g	2000.0 g	2000.0 g	1999.9 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
13 g	34 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a formal and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — **Customer**

04/21/2023 — **Authorized By**

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — ilac-MRA
International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-C026604949

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	AX8201N/E	C026604949	16

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 64.6 F.° **R.H.** 24 %
END TEMP 64.6 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

8200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	4000 g	8000 g
1. Prior to Service	50.0 g	100.0 g	3999.8 g	7999.7 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	4000.0 g	8000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 0.0 g	3 -0.1 g
			1 +0.1 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer
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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143813721

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX622	C143813721	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.2 **F.° R.H.** 24 **%**
END TEMP 65.2 **F.°**
TEMP GAUGE S/N 221227554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	300.00 g	599.97 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

Corner Load	Weight Used	Prior to Service		
	200g		2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — **Customer**

04/21/2023 — **Authorized By**

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-8342411385

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	SPX621	8342411385	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.5 F.° R.H. 24 %
END TEMP 65.5 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.0 g	10.0 g	300.4 g	600.9 g
Tolerance Error	0.0 g	0.0 g	0.0 g	+0.9 g
2. After Service	5.0 g	10.0 g	300.0 g	600.0 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

200.0 g	200.0 g	200.0 g	200.0 g	200.0 g	200.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

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CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Report ID#: 04.21.23.2690-C130255345

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX622	C130255345	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.2 F.° R.H. 24 %
END TEMP 65.2 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	299.98 g	599.97 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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Analytical & Precision Balance Co., Inc.
The Weighing Solution
ANSI/ISO/IEC 17025 Accredited / GSA Contract Holder
9830 S. 51st Street, Suite B-103 • Phoenix, AZ 85044
(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C144874060

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 113th Avenue	Main / Lab

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX622	C144874060	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.0 **F.° R.H.** 24 **%**
END TEMP 65.0 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	299.98 g	599.92 g
Tolerance Error	0.00 g	0.00 g	0.00 g	-0.08 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT, Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023
Customer

04/21/2023
Authorized By

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Form # 1987 Rev. 8-20

End of Report

Original: Vendor Copy: Customer

Analytical & Precision Balance Co., Inc.
The Weighing Solution
ANSI/ISO/IEC 17025 Accredited / GSA Contract Holder
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(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143813728

International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C143813728	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.0 **F.°** **R.H.** 24 **%**
END TEMP 65.0 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	299.97 g	599.95 g
Tolerance Error	0.00 g	0.00 g	0.00 g	0.00 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

Corner Load	Weight Used	Prior to Service	2 0.00 g	3 0.00 g
	200g		1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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Analytical & Precision Balance Co., Inc.
The Weighing Solution
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(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143813872

IAS ACCREDITED — ilac-MRA
International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	(2012 N 11th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	STX622	C143813872	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.3 **F.°** **R.H.** 24 **%**
END TEMP 65.3 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.01 g — Capacity/Resolution
+/-0.05 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.00 g	10.00 g	299.96 g	599.94 g
Tolerance Error	0.00 g	0.00 g	0.00 g	-0.06 g
2. After Service	5.00 g	10.00 g	300.00 g	600.00 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g
Corner Load		After Service	2 0.00 g	3 0.00 g
			1 0.00 g	4 0.00 g

Repeatability Readings

200.00 g	200.00 g	200.00 g	200.00 g	200.00 g	200.00 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.0029 g	0.0058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer
04/21/2023 — Authorized By

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Form # 1987 Rev. 8-20 — End of Report — Original: Vendor Copy: Customer

Analytical & Precision Balance Co., Inc.
The Weighing Solution
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(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-8342411401

IAS ACCREDITED
International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	SPX621	8342411401	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 64.3 **F.°** **R.H.** 24 **%**
END TEMP 64.3 **F.°**
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.0 g	10.0 g	300.3 g	600.6 g
Tolerance Error	0.0 g	0.0 g	0.0 g	+0.6 g
2. After Service	5.0 g	10.0 g	300.0 g	600.0 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

200.0 g	200.0 g	200.0 g	200.0 g	200.0 g	200.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023
Customer

04/21/2023
Authorized By

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Form # 1987 Rev. 8-20

End of Report

Original: Vendor Copy: Customer

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Analytical & Precision Balance Co., Inc.
The Weighing Solution
AASI/ISO/IEC 17025 Accredited / GSA Contract Holder
9830 S. 51st Street, Suite B-103 • Phoenix, AZ 85044
(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-8342411384

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

ilac-MRA

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 11th Avenue	Main / Lab
Mfgr.:	**Model:**	**Serial #:**	**Equipment #:**
Ohaus	SPX621	8342411384	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 64.3 F.° **R.H.** 24 %
END TEMP 64.3 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

620 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

20212371I

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	5 g	10 g	300 g	600 g
1. Prior to Service	5.0 g	10.0 g	300.4 g	600.8 g
Tolerance Error	0.0 g	0.0 g	0.0 g	+0.8 g
2. After Service	5.0 g	10.0 g	300.0 g	600.0 g

	Weight Used			
Corner Load	200g	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

200.0 g	200.0 g	200.0 g	200.0 g	200.0 g	200.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☐ This instrument was within tolerance and customer specifications
☑ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

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04/21/2023 — Customer

04/21/2023 — Authorized By

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Form # 1987 Rev. 8-20

End of Report

Original: Vendor Copy: Customer

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Analytical & Precision Balance Co., Inc.
The Weighing Solution
ANSI/ISO/IEC 17025 Accredited / GSA Contract Holder
9830 S. 51st Street, Suite B-103 • Phoenix, AZ 85044
(480) 598-0321 • (800) 934-4451 • E-mail: info@apscales.com • Website: apscales.com

CERTIFICATE OF CALIBRATION

ISO 17025 ACCREDITED

Report ID#: 04.21.23.2690-C143820256

IAS ACCREDITED — International Accreditation Service
Calibration Laboratory # CL-104

Customer Name:	Customer #:	Address:	Bldg.: / Room:
Women's International Pharmacy	2690	12012 N 111th Avenue	Main / Non Sterile

Mfgr.:	Model:	Serial #:	Equipment #:
Ohaus	STX6201	C143820256	N/A

AZ RSR License #00 2484
AZ RSA License #014790
START TEMP 65.5 F.° **R.H.** 24 %
END TEMP 65.5 F.°
TEMP GAUGE S/N 221727554

Cal. Date: 04/21/2023
Recall Date: 04/30/2024

6200 g / 0.1 g — Capacity/Resolution
+/-0.5 g — Tolerance Value

All ISO 17025 accredited calibrations performed by Analytical & Precision Balance Co., Inc. RSR are done using N.I.S.T. Traceable weight standards issued from an ISO 17025:2017 Accredited Metrology Laboratory. These weight standards are submitted to the Metrology Lab on an annual basis. The Metrology Weight Reports are available upon client's request. The Traceable Certificate Number issued for the weight standards used during this calibration:

202123711

Calibration Instructions: Internal Cal. ☐ External Cal. ☑ Standard Cal. Procedure ☑ Handbook 44 ☐

List Weights Used	50 g	100 g	3000 g	6000 g
1. Prior to Service	50.0 g	100.0 g	2999.8 g	5999.7 g
Tolerance Error	0.0 g	0.0 g	0.0 g	0.0 g
2. After Service	50.0 g	100.0 g	3000.0 g	6000.0 g

	Weight Used			
Corner Load	2kg	Prior to Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g
Corner Load		After Service	2 0.0 g	3 0.0 g
			1 0.0 g	4 0.0 g

Repeatability Readings

2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g	2000.0 g

*CORNER-LOAD ECCENTRICITY (TYPE B UNCERTAINTY) ☑ *LINEARITY (TYPE A UNCERTAINTY) ☑ *REPEATABILITY (TYPE A UNCERTAINTY) ☑

Combined Uncertainty	Expanded Uncertainty
0.029 g	0.058 g

Comments:

1. Prior to Service:
☑ This instrument was within tolerance and customer specifications
☐ This instrument was NOT within tolerance and customer specifications

2. After Service:
☑ This instrument IS WITHIN TOLERANCE and customer specifications
☐ This instrument is OUT OF TOLERANCE: DO NOT USE THIS INSTRUMENT. Significant out of tolerance may affect end product.

Analytical & Precision Balance Co., Inc. has developed a format and procedure for the estimation of uncertainty of all calibrations that it does. The Combined Type A and B Uncertainty Report includes the standard deviation on repeatability measurements and worst-case eccentricity. The reported Expanded Uncertainty of Measurement is stated with a Coverage Factor of k=2 with a provided level of confidence: approximately 95%. Measurements reported are traceable to SI units via standards traceable to N.I.S.T. The report containing all the Uncertainty Calculations is a separate report and is available at client's request for an additional fee. This Certificate of Calibration applies only to the specific instrument identified by the serial #. Each client should analyze their Certificate of Calibration to determine impact to their scope of business. Simple Acceptance Decision Rule; WITHIN TOLERANCE or OUT OF TOLERANCE does not take Expanded Uncertainty of Measurement into account.

04/21/2023 — Customer

04/21/2023 — Authorized By

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Medisca

CERTIFICATE OF ANALYSIS

ESTRIOL, USP (Micronized)

Batch/Lot Number	199036
Manufacturing Date	03/11/2023
Expiration Date	02/28/2026
CAS:	50-27-1

This lot was manufactured by:

ZHEJIANG XIANJU
PHARMACEUTICAL CO., LTD.
(FENGXI)
15 WEST FENGXI ROAD
XIANJU, TAIZHOU, ZHEJIANG, 317300
CN

TESTS	SPECIFICATIONS	RESULTS
SOURCE	Soy	
SOLUBILITY	Insoluble in water; sparingly soluble in alcohol, soluble in acetone, in chloroform, in dioxane, in ether, and in vegetable oils	
PACKAGING AND STORAGE	Preserve in tight, light resistant containers	

*TESTED ON 07/03/2023

Lot number has been changed from DC061-230303 to 199036.

LOT TESTED BY:

LEO Analytical Laboratory Inc.
3541 W Bethany Rd Unit 130
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

06/31/2023

ISSUE DATE:

07/06/2023

The above mentioned product conforms to the specification of USP

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by the Medisca. This lot was manufactured by M-777607

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been reviewed and approved through MEDISCA's Quality Management System.

QA APPROVED

Record Code	Effective Date
ACP127-D7R01	2021-01-01

Zhejiang Xianju Pharmaceutical Co., Ltd
Certificate of Analysis

Product	Estriol	Batch No	Z200101
Batch No	QC081-230310	Test Date	2023-05-07
Amount	16.250kg	Manufacture Date	2023-03-11
According To	USP 2020-05-01 And Customer Standard	Retest Date	2026-03-11

ITEM	SPECIFICATION	RESULT
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	A. Complies by IR	Conforms
Identification	B. Complies by HPLC	Conforms
Specific Rotation	+81° ~ +82°	+81.0°
Residue On Ignition	≤0.1%	0.06%
Loss On Drying	≤0.5%	0.2%
Related Substances	16A, 17a-Estriol≤0.5%	Not detected
Related Substances	Estriol related compound A≤0.5%	0.01%
Related Substances	16β-Estriol≤0.5%	0.07%
Related Substances	17b-Estriol≤0.5%	Not detected
Related Substances	Estrone≤0.5%	Not detected
Related Substances	Estradiol≤0.5%	Not detected
Related Substances	3-O-Methyl estriol≤0.5%	Not detected
Related Substances	Any individual impurity ≤0.10%	0.07%
Related Substances	Total impurities(include estriol related compound A) ≤1%	0.22%
Residual Solvents	Methanol≤3000ppm	40ppm
Residual Solvents	Acetone≤5000ppm	Not detected
Residual Solvents	Ethyl acetate≤5000ppm	6ppm
Residual Solvents	Cyclohexane≤3880ppm	Not detected
Assay	Contains 97.0% to 102.0% (C18H24O3 calculated on the dried basis	100.1%
Particle Size (Volume Method)	D90≤10μm	8μm

Conclusion: The Product Conforms To USP 2020-05-01 And Customer Standard.

Reported by: 王永林
Date: 2023-05-25

Checked by:
Date: 2023-05-25

Address: 18 West Fengji Road, Modern Industrial Park, Xianju, Zhejiang, China
Email: info@zjpharma.com

COPY

QA APPROVED

Letco MED

Letco Medical, LLC

DATE CREATED	REVISION	PAGE
April 21, 2023	00	1 of 3

CERTIFICATE OF ANALYSIS

Invoice # VF-3510

Qty. Rcv'd 1 x 5gm

Date Rcv'd 05/01/2023

RPs Initials JB

Letco Item	691055	691056
Letco Lot	2303150009	2303150010

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Levothyroxine Sodium USP	4001/3/001/23	February 18, 2023	February 17, 2026

	TEST	SPECIFICATION	RESULT
	Description	Light yellow to Buff colored, hygroscopic powder.	Buff colored, hygroscopic powder
	Solubility		
	In Sodium hydroxide	Soluble in solutions of sodium hydroxide	Complies
	In Sodium carbonate	Soluble in hot solution of sodium carbonate	Complies
	In Ethanol	Slightly soluble in ethanol	Complies
	In Water	Very slightly soluble in water	Complies
	In Acetone	Insoluble in acetone	Complies
	In Chloroform	Insoluble in chloroform	Complies
	In Ether	Insoluble in ether	Complies
	pH (0.1% w/v aqueous solution)	About 8.9	9.05
	Identification By		
*	A) IR	The IR absorption spectrum of sample should conform to that of standard.	Complies
*	B) HPLC	The retention time of the major peak of the sample solution should correspond to that of the standard solution, as obtained in the assay.	Complies
*	C) Test for Sodium	The sample Solution meets the requirements of the pyroantimonate precipitation test.	Complies
*	Specific Optical Rotation (°) @ 25°C (on Anhydrous basis)	Between -5 and -6	-5.50
*	Water Content by KF (%w/w)	Not more than 11.0	9.14
	Organic Impurities by HPLC (% w/w as per Procedure -2)		
*	a) Liothyronine	Not more than 1.0	0.06
*	b) Monochlorotriiodothyronine	Not more than 0.15	Not Detected
*	c) Triiodothyroacetic acid, or T3-Acetic acid	Not more than 0.15	BRL
*	d) O-(4-Hydroxy-3,5-diiodophenyl) thyroxine, or T6	Not more than 0.50	Not Detected

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

Letco MED

Letco Medical, LLC

DATE CREATED	REVISION	PAGE
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CERTIFICATE OF ANALYSIS

Letco Item	691055	691056					
Letco Lot	2303150009	2303150010					

*	e) T4-Acetic acid	Not more than 0.30	BRL
*	f) T4- Formic acid N-methylamide	Not more than 0.30	Not Detected
*	g) Tetraiodothyrobenzoic acid or T4- Benzoic acid	Not more than 0.15	Not Detected
*	h) Individual unspecified impurity	Not more than 0.10	0.05
*	i) Total Impurities	Not more than 2.0	0.11
*	Levothyroxine N-methylamide Content (% w/w)	Not more than 0.15	BRL
*	Assay by HPLC (% w/w) (on Anhydrous basis)	Not less than 97.0 and Not more than 103.0	99.3
	Residual solvents (by HPLC) Test: I (ppm)		
*	Acetic acid	Not more than 5000	Not Detected
	Residual Solvents (By Headspace GC) Test: II (ppm)		
*	Methanol	Not more than 3000	BDL
*	Acetone	Not more than 5000	Not Detected
*	Isopropyl Alcohol	Not more than 5000	BDL
*	Acetonitrile	Not more than 410	BDL
*	Methyl isobutyl ketone	Not more than 4500	Not Detected
*	Toluene	Not more than 890	BDL
*	Anisole	Not more than 5000	Not Detected
	Residual Solvents (by Headspace GC) Test: III (ppm)		
*	Triethyl amine	Not more than 320	Not Detected

ADDITIONAL INFORMATION

** Verification testing performed by Letco Medical is represented by an astertsk*

Chemical name of Impurities:
Monochlorotriiodothyronine: (*S*)-2-Amino-3-(3-chloro-4-(4-hydroxy-3,5-diiodophenoxy)-5-iodophenyl)propanoic acid.
Levothyroxine N-methylamide: (*S*)-2-Amino-3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]-N-methylpropanamide
Triiodothyroacetic acid, or T3-Acetic acid: [4-(4-Hydroxy-3-iodophenoxy)-3, 5-diiodophenyl] acetic acid
***O*-(4-Hydroxy-3,5-diiodophenyl) thyronine, or T6:** (*S*)-2-Amino-3-[4-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenoxy]-3,5-diiodophenyl]propanic acid
T4-Acetic acid: 2-(4-(4-Hydroxy-3,5-diioophenoxy)-3,5-diiodophenyl) acetic acid
T4 Formic acid N-methylamide: 4-(4-Hydroxy -3, 5-diiodophenoxy)-3,5-diiodo-N-methylbenzamide
Tetraiodothyrobenzoic acid or T4-Benzoic acid: 4-(4-Hydroxy -3,5-diiodophenoxy)-3,5-diiodobenzoic acid

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

Letco MED

Letco Medical LLC

DATE CREATED	REVISION	PAGE
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CERTIFICATE OF ANALYSIS

Letco Item	691055	691056					
Letco Lot	2303150009	2303150010					

Packaging and Storage Conditions: Store at 2°C to 8°C, preserve in tight container and protected from light.

Manufacturer Remarks: The Material Complies with the above Specification.

This product is manufactured by Azico Biophore India Private Limited, Plot No. 40/A, J.N. Pharma City, Parawada Mandal, Visakhapatnam, Andhra Pradesh 531021, India (IND)

LETCO QA REVIEW: Robin Owens

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

AZICO BIOPHORE

DL 10/12/2023

COPY

Azico Biophore India Pvt. Ltd
425/8RT, Door No. 7-1-621/828
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTC061809
+91-40-2381 0385 / 23705066
+91-40-2381 2709
info@Azicobiophore.com

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM		
Reference	USP	Mfg. Date	18/02/2023
Batch No.	4001/3/001/23	Expiry Date	17/02/2026
Date of Analysis	17/03/2023	Dispatch Qty	400.00 gm.
Name of the Customer	M/s. L.G.M Pharma.		

S. No	Test	Specification	Result
1.	Description	Light yellow to Buff colured, hygroscopic powder.	Buff colured, hygroscopic powder.
2.	Solubility		
	In Sodium hydroxide	Soluble in solutions of sodium hydroxide	Complies
	In Sodium carbonate	Soluble in hot solution of sodium carbonate	Complies
	In Ethanol	Slightly soluble in ethanol	Complies
	In Water	Very slightly soluble in water	Complies
	In Acetone	Insoluble in acetone	Complies
	In Chloroform	Insoluble in chloroform	Complies
	In Ether	Insoluble in ether	Complies
3.	pH (0.1%w/v aqueous solution)	About 8.9	9.05
4	Identification By		
	A) IR	The IR absorption spectrum of sample should conform to that of standard.	Complies
	B) HPLC	The retention time of the major peak of the sample solution should correspond to that of the standard solution, as obtained in the assay.	Complies
	C) Test for Sodium	The sample Solution meets the requirements of the pyroantimonate precipitation test.	Complies
5.	Specific Optical Rotation(°) @ 25°C (on Anhydrous basis)	Between -5 and -6	-5.50
6.	Water Content by KF (%w/w)	Not more than 11.0	9.14

	Prepared By	Checked By	Approved By
Name	G.V.S.R. Ramesh	E. Naga Brahmam	Baburao Koyyagura
Designation - Dept.	Chemist- QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	18/03/2023	18/03/23	18/03/2023

Format No: QAD/032-F01-00

PLOT NO.: 49/A, J.N. PHARMA CITY, PARAWADA MANDAL, ANAKAPALLI, A.P. INDIA

Letco QA REVIEWED
Initial/Date: 4/21/23
Date Format: D-M-Y
Tracking #: 23042004

Calculating Levothyroxine (T4) loss on drying potency

(as per USPC vol. 14 no. 4 p. 306)

Lot: 2303150010 Manufacturer: Letco

Date: 8/1/2023 EXP: 2/17/2026

Standard Conversion of 'sodium' to 'base' (MW 776.87/798.65)

Conversion: 97.20%

TEST 1 Loss on drying % = 9.14%

TEST 2 Assay % 99 = 99.30%

STEP 1	100%	-	Loss on drying	=	Dried levothyroxine sodium %
STEP 2	Dried levo %	x	Assay %	=	Levothyroxine Sodium USP potency
STEP 3	Levo Sodium%	x	97.2% (standard base conversion)	=	Levothyroxine USP potency

100%	-	9.14% Loss on drying %	=	90.86%	Dried levothyroxine sodium %
90.86% Dried levo sodium%	x	99.30% Assay %	=	90.22%	Levothyroxine Sodium USP potency
90.22% Levo sodium%	x	97.20% 97.2% (standard base conversion)	=	87.70%	Levothyroxine USP potency

**Excel program automatically converts to percent - when checking by calculator you must divide the answer by 100.*

Calculating potency adjustment factor:

want	Potency %	x	Adjustment factor	=	100%
therefore	100%	÷	Potency %	=	Adjustment factor

**This is a factor not a percent*

If potency is under 100%	100%	÷	87.70% Low potency %	=	1.140 Adjustment in decimal form	Use loss on drying adjustment

**This number is what we multiply with the theoretical weight to get the actual weight*

RPH signature #1 — 8012023 date

RPH signature #2 — 8-1-23 date

AZICO BIOPHORE

Azico Biophore India Pvt. Ltd
425/3&7, Door No. 7-1-621/328
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTRC051409
+91-40-2381 0385 / 23705066
+91-40-2381 2709
info@Azicobiophore.com

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM		
Reference	USP	Mfg. Date	18/02/2023
Batch No.	4001/3/001/23	Expiry Date	17/02/2026
Date of Analysis	17/03/2023	Dispatch Qty.	400.00 gm.
Name of the Customer	M/s. L.G.M Pharma.		

S. No	Test	Specification	Result
7.	Organic Impurities By HPLC (% w/w as per Procedure-2)		
	a) Liothyronine	Not more than1.0	0.06
	b) Monochlorotriiodothyronine	Not more than 0.15	Not Detected
	c) Triiodothyroacetic acid, or T3-Acetic acid	Not more than 0.15	BRL
	d) O-(4-Hydroxy-3,5-diiodophenyl) thyroxine, or T6	Not more than 0.50	Not Detected
	e) T4-Acetic acid	Not more than 0.30	BRL
	f) T4- Formic acid N-methylamide	Not more than 0.30	Not Detected
	g) Tetraiodothyrobenzoic acid or T4- Benzoic acid	Not more than 0.15	Not Detected
	h) Individual unspecified impurity	Not more than 0.10	0.05
	i) Total Impurities	Not more than 2.0	0.11
8.	Levothyroxine N-methylamide Content (%,w/w)	Not more than 0.15	BRL
9.	Assay By HPLC (%w/w) (On Anhydrous basis)	Not less than 97.0 and Not more than 103.0	99.3
10	Residual solvents(by HPLC) Test: I (ppm)		
	Acetic acid	Not more than 5000	Not detected
11	Residual Solvents (By Headspace GC) Test: II (ppm)		
	a) Methanol	Not more than 3000	BDL
	b) Acetone	Not more than 5000	Not detected
	c) Isopropyl Alcohol	Not more than 5000	BDL
	d) Acetonitrile	Not more than 410	BDL
	e) Methyl isobutyl ketone	Not more than 4500	Not detected
	f) Toluene	Not more than 890	BDL
	g) Anisole	Not more than 5000	Not Detected

	Prepared By	Checked By	Approved By
Name	G.V.S.R. Ramesh	E. Naga Brahmam	Baburao Koyyagura
Designation - Dept.	Chemist- QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	18/03/2023	18/03/23	18/03/2023

PLOT NO.: 49/A, J.N. PHARMA CITY, PARAWADA MANDAL, ANAKAPALLI, A.P. INDIA

AZICO BIOPHORE

Azico Biophore India Pvt. Ltd
125/8RT, Door No. 7-1-622/328
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTC061809
+91-40-2381 0385 / 23705044
+91-40-2381 2709
info@Azicobiophore.com

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM		
Reference	USP	Mfg. Date	18/02/2023
Batch No.	4001/3/001/23	Expiry Date	17/02/2026
Date of Analysis	17/03/2023	Dispatch Qty.	400.00 gm.
Name of the Customer	M/s. L.G.M Pharma.		

S. No	Test	Specification	Result
12.	Residual Solvents (By Headspace GC) Test: III (ppm)		
	a) Triethyl amine	Not more than 320	Not Detected

Chemical name of Impurities:

Monochlorotriiodothyronine: (*S*)-2-Amino-3-(3-chloro-4-(4-hydroxy-3, 5-diiodophenoxy)-5-iodophenyl)propanoic acid.

Levothyroxine *N*-methylamide: (*S*)-2-Amino-3-[4-(4-hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenyl]-N-methylpropanamide

Triiodothyroacetic acid, or T3-Acetic acid: [4-(4-Hydroxy-3-iodophenoxy)-3, 5-diiodophenyl] acetic acid.

***O*-(4-Hydroxy-3, 5-diiodophenyl) thyroxine, or T6:** (*S*) 2-Amino-3-[4-[4-(4-hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenoxy]-3, 5- diiodophenyl]propanoic acid.

T4-Acetic acid: 2-(4-(4-Hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenyl) acetic acid.

T4 Formic acid *N*-methylamide: 4-(4-Hydroxy -3,5-diiodophenoxy)-3,5-diiodo-*N*-methylbenzamide.

Tetraiodothyrobenzoic acid or T4-Benzoic acid: 4-(4-Hydroxy -3,5-diiodophenoxy)-3,5-diiodobenzoic acid.

Packaging and Storage Conditions: Finished product shall be packed in transparent LDPE bag with nitrogen purging, and tied with nylon strip followed by black LDPE bag along with silica gel desiccant and tied with nylon strip followed by triple laminated bag along with O-buster and hot seal and followed by HDPE container.

Store at 2°C to 8°C, preserve in right container and protected from light.

Remarks: The Material Complies as per the above Specification.

	Prepared By	Checked By	Approved By
Name	G.V.S.R. Ramesh	E. Naga Brahmam	Baburao Koyyagura
Designation - Dept.	Chemist- QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	18/03/2023	18/03/23	18/3/2023

PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, ANAKAPALLI, A.P. INDIA

spectrum® CHEMICAL MFG CORP

Certificate Of Analysis

Item Number	ES200	Lot Number	LI00864
Item	Estrone, USP	Manufacture Lot	190807
CAS Number	53-16-7	Manufacturer Code	4856
Molecular Formula	$C_{18}H_{22}O_2$	Molecular Weight	270.37

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY ($C_{18}H_{22}O_2$; DRIED BASIS)	97.0	103.0 %	99.8 %
CLARITY OF SOLUTION	SOLUTION IS CLEAR		SOLUTION IS CLEAR
SPECIFIC ROTATION [a]D25	+158° to +165°		+162.3°
LOSS ON DRYING		0.5 %	0.1 %
RESIDUE ON IGNITION		0.5 %	0.04 %
EQUILENIN AND EQUILIN	LESS RED COLOR THAN STANDARD		LESS RED COLOR THAN STANDARD
ORDINARY IMPURITIES		2.0 %	<2.0 %
ELEMENTAL IMPURITIES:			
LITHIUM (Li)	AS REPORTED		<0.03 µg/g
IDENTIFICATION A (FTIR)	MATCHES FTIR STANDARD		MATCHES FTIR STANDARD
IDENTIFICATION (B)	MATCHES UV STANDARD		MATCHES UV STANDARD
EXPIRATION DATE			14-AUG-2024
DATE OF MANUFACTURE			14-AUG-2019
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 3 (solvent) / ETHANOL			<5000 ppm

DL 10/9/2023

COPY

Certificate of Analysis Results Entered By:

HBERMUDEZ
Hernan Bermudez
07-NOV-19 14:19:07

Certificate of Analysis Results Approved By:

HBERMUDEZ
Hernan Bermudez
07-NOV-19 14:20:04

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Zhejiang Xianju Pharmaceutical Co. Ltd. at No. 1 Xianyao Road, Xianju, Zhejiang 317300, China. Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

SPL Labs

TN/01/92023

COPY

1850 E. Riverview Dr. Phoenix, AZ 85034
602.900.0120
Fax 480.513.1026

Certificate of Analysis

Same lot

Product Name	Thyroid, Full Strength	Lot Number	H22212-FSV
Date of Manufacture	11/21/2022	Expiration Date	11/21/2024

The undersigned hereby certifies the following data to be true representation of the obtained results of tests and assays.

Chemical Analysis	Result	Units	Specification	Method Reference
*Fat	8.0	%	Report value	AOAC
*Loss on Drying	5.8	%	NMT 6.0	USP <731>
*Inorganic Iodides	NMT 0.01	%	NMT 0.01	USP
Assay – T3 (Liothyronine)	33.2	mcg/gr	22.5 – 36	USP
Assay – T4 (Levothyroxine)	134.8	mcg/gr	95 - 152	USP
Identification	PASS	—	Pass	USP
*Residual Solvents - Heptane	<500	ppm	Report Value†	USP <467>
*Residual Solvents - Isopropanol	47,500	ppm	Report Value†	USP <467>

†Class 1 and 2 solvents are not utilized in the manufacturing of this API. Class 3 solvents utilized in the manufacturing process are identified and quantified on this document for reporting purposes. Although USP <467> limits the residual solvent content of a finished drug product, it does not apply directly to excipients, drug substances, or dietary ingredients except where specified in the individual monographs. It is the responsibility of the compounder or manufacturer of the finished product to ensure that the total residual solvent content meets relevant requirements of the permitted daily exposure within USP <467>.

Microbiological Analysis	Result	Units	Specification	Method Reference
**Salmonella spp.*	Not Detected	—	Absent	USP <61>, USP <62>
**E. coli*	Not Detected	—	Absent	USP <61>, USP <62>

Assay results are "as is", not corrected for moisture.

*: Tested by outside laboratory

Invoice # 230051-A
Qty. Rcv'd 2x1kg 6-8-23
Date Rcv'd 6-8-23
RPM/Initials

Manufacturer: Specialty Process Labs
Source: Porcine, United States of America/Canada
FALCPA 2004 Allergens: None

Quality Assurance

03/15/2023
Date Signed

S·P Labs

Phoenix, AZ 85034
602.900.0120

SPL Class 3 Solvent Presence Calculation for Thyroid, Full Strength API (adendum to Thyroid, Full Strength C of A)

Class 3 solvents are considered less toxic, and control to 50 mg/day or less for each of these solvents are acceptable without justification.

USP <467> limits the residual solvent content of a finished drug product, it does not apply directly to excipients, drug substances, or dietary ingredients except where specified in the individual monographs.

It is the responsibility of the compounder or manufacturer of the finished product to ensure that the total residual solvent content meets relevant requirements of the permitted daily exposure within USP <467>.

Class 3 Permitted Daily Exposure: 5,000 ppm = 50 mg/day "allowance" BASED on 10,000 mg Daily Dosage

Solvent	Amount	Solvent % Equivalent	Thyroid Daily Dosage Equiv.	Class 3 Solvent Daily Presence	
Class 3	1 ppm	0.0001%	N/A	N/A	N/A
Class 3	5,000 ppm	0.5000%	10,000.00 mg	50 mg/Day	5,000 ppm
IPA*	47,500 ppm	4.7500%	19.17 mg	0.911 mg/Day	91 ppm @ 1 Grains/Day (as FS)
IPA*	47,500 ppm	4.7500%	115.04 mg	5.465 mg/Day	546 ppm @ 6 Grains/Day (as FS)
IPA*	47,500 ppm	4.7500%	958.70 mg	45.538 mg/Day	4,554 ppm @ 50 Grains/Day (as FS)
Heptane*	500 ppm	0.0500%	115.04 mg	0.058 mg/Day	6 ppm @ 1 Grains/Day (as FS)
Heptane*	500 ppm	0.0500%	249.26 mg	0.125 mg/Day	12 ppm @ 6 Grains/Day (as FS)
Heptane*	500 ppm	0.0500%	958.70 mg	0.479 mg/Day	48 ppm @ 50 Grains/Day (as FS)

*Tested by Outside Laboratory

Thyroid USP Concentration Factor: 3.39

65.00 mg/Day = 1 Grain
19.17 mg/Day (as FS)= 1 Grain
115.04 mg/Day (as FS)= 6 Grains
249.26 mg/Day (as FS)= 13 Grains
958.70 mg/Day (as FS)= 50 Grains

Thyroid, Full Strength API Lot #: [redacted]

Typical Daily dose (of Thyroid USP) per 1 kg (2.2 lbs) of body weight (for Congenital Hypothyroidism) = 1.2 - 1.8 mg for age Over 12 Years**

Example, based on: 217 kg person (477 lb equiv.), this would be equivelent to 390.00 mg dosage Thyroid USP/Day

390.00 mg dosage Thyroid USP/Day is equivelent to 6.00 Grains dosage Thyroid USP/Day (@ 1 Grain = 65 mg Thyroid USP (per USP))

Our example is to demonstrate that above person weight is not a typical average weight for an individual and thus @ 6 Grains/Day is NOT a typical MAX dosage amount for an average individual. Thus, this is the basis for using 6 Grains/Day (as max) in determining the IPA/Heptane PPM/Daily presence.

**dosage indication from Nature-Throid; Armour; NP-Thyroid Prescribing Information

01/12/2023
Date Signed

Quality Assurance

Nonsterile Compounded Products with extended BUD

Bracketed study performed for single ingredients:

Compounded in our standard cream base.

Estrone -- 0.5 and 10 mg/gm

Estradiol 0.7 and 20 mg/gm

Estriol 0.5 and 100 mg/gm

Progesterone 2 and 200 mg/gm

Dhea 1.25 and 200 mg/gm

7-Keto-Dhea 1 and 100 mg/gm

Hydrocortisone 5 and 100 mg/gm

Pregnenolone 1 and 200mg/gm

Chrysin 5 and 200 mg/gm

Testosterone 0.5 and 200 mg/gm

All formulations remained stable for 180 days, assigned 180 day BUD

Combined Estrone, Estradiol, Estriol, Progesterone, Dhea, 7-keto Dhea, Hydrocortisone, Pregnenolone, Chrysin, Testosterone into 1 formulation in our standard cream base - potency over time testing performed for 360 days and formulation remained stable. Assigned 180 day BUD.

Testing performed by CIAL using UHPLC coupled with PDA (Ultra-High Performance Liquid Chromatography coupled with Photodiode Array detection). Individual lab reports certificate of analysis can be viewed during inspection visit.

Name	Strength	Beyond Use Date	Storage Conditions
ALPROSTADIL (5 ML)	100 MCG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	10 MCG/30 MG/1 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	10 MCG/30 MG/4 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	100 MCG/30 MG/6 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	20 MCG/30 MG/2 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	40 MCG/30 MG/4 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	6 MCG/15 MG/0.25 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	60 MCG/30 MG/6 MG/ML	45	KEEP FROZEN
ALPROSTADIL/PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	8.3 MCG/22.5 MG/0.83 MG/ML	45	KEEP FROZEN
PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	30/1 MG/ML	45	KEEP FROZEN
PAPAVERINE HCL/PHENTOLAMINE MESYLATE (5 ML)	30/4 MG/ML	45	KEEP FROZEN
PHENYLEPHRINE HCL (2 ML)	1 MG/ML	60	ROOM TEMPERATURE
SERMORELIN ACETATE (10 ML)	0.5 MG/ML	60	ROOM TEMPERATURE
SERMORELIN ACETATE (10 ML)	1 MG/ML	60	ROOM TEMPERATURE
SERMORELIN ACETATE (10 ML)	2 MG/ML	60	NONHAZARDOUS
METHYLCOBALAMIN (10 ML)	10 MG/ML	60	PROTECT FROM LIGHT; ROOM TEMPERATURE
NICOTINAMIDE ADENINE DINUCLEOTIDE (NAD+) (5 ML)	200 MG/ML	60	REFRIGERATE
TESTOSTERONE CYPIONATE/ANASTROZOLE GRAPESEED OIL (4 ML)	200/0.5 MG/ML	60	ROOM TEMPERATURE
TESTOSTERONE CYPIONATE/ANASTROZOLE GRAPESEED OIL (4 ML)	200/1 MG/ML	60	ROOM TEMPERATURE
TESTOSTERONE CYPIONATE/DHEA GRAPESEED OIL (1 ML)	50/5 MG/ML	60	ROOM TEMPERATURE
TESTOSTERONE CYPIONATE/DHEA GRAPESEED OIL (4 ML)	200/10 MG/ML	60	ROOM TEMPERATURE
GONADORELIN ACETATE (5 ML)	0.2 MG/ML	120	PROTECT FROM LIGHT; ROOM TEMPERATURE

Invoice # BPT205701004-01A
Qty. Rcv'd 1 x 1gm
Date Rcv'd 08/16/2023
RPh Initials MT

QA APPROVED

biopeptek

CERTIFICATE OF ANALYSIS

Reference document: BPT-QC-STP-3113 V01

Product Name		Alprostadil		
CAS		745-65-3		
Molecule Formular		$C_{20}H_{34}O_5$		
Lot No.		GSM11320221002		
Storage Conditions		For less than 6-month storage, the recommended condition is 2-8℃. For longer term (> 6-month) storage, the recommended condition is minus 20℃.		
Test Items		**Specifications**	**Results**	**Method**
Appearance		White or slightly yellowish crystalline powder	White or slightly yellowish crystalline powder (Conforms)	BPT-QC-SOP-3113 V01
Identification	**IR Spectral**	The infrared spectroscopy is concordant with that of the reference standard.	Conforms	BPT-QC-SOP-3113 V01; USP<197M>
Specific Tests	**Residue on Ignition**	≤0.5%	0.03%	BPT-QC-SOP-3113 V01; USP<281>
	Limit of Chromium	≤0.002%	Conforms	BPT-QC-SOP-3113 V01
	Limit of Rhodium	≤0.002%	Conforms	BPT-QC-SOP-3113 V01
	Related Substances(HPLC)	Prostaglandins A_1: ≤ 1.5% Prostaglandins B_1: ≤ 0.1% Any foreign prostaglandin impurity eluting before Prostaglandin A_1: ≤ 0.9% Impurity at relative retention time 0.6, relative to Prostaglandin A_1: ≤ 0.9% Sum of the impurities at relative retention times 2.0 and 2.3, ≤ 0.8% Any other foreign prostaglandins impurity eluting after prostaglandin A_1: ≤ 0.9% Total impurities: ≤ 7.0%	N.D N.D 0.25% 0.275% N.D 0.230% 0.777%	BPT-QC-SOP-3113 V01
	Water Content	≤0.5%	0.15%	BPT-QC-SOP-3113 V01; USP<921>
Assay		95.0%~105.0%(calculated on anhydrous basis)	99.0%	BPT-QC-SOP-3113 V01
Conclusion	This batch was tested following the *analytical procedure of BPT-QC-SOP-3113 V01 and USP Alprostadil Monograph, DocId GUID-C5DADF43-94B8-47AC-98A2-19688A27476B_5_en-US* The test results met the *specifications of BPT-QC-STP-3113 V01.*			
Date of Mfg	02 Oct 2022	Date of Exp	01 Oct 2025	
Date of Test	07 Nov 2022	Date of Release	07 Nov 2022	
Quality Control: Nana Zhang	Nana Zhang 07 Nov 2022 Reviewed	Quality Assurance: Yongna Zhao	Yongna Zhao 07 Nov 2022 Approved	

Biopeptek Pharmaceuticals,LLC

Corporate headquarters: 5 Great Valley Parkway, Suite 100 Malvern, PA 19355, U.S.A Tel: 610.643.4881 www.biopeptek.com

Manufactured and Packaged at the FDA registered facility: 218 Shuangyuan Road, Chengyang, Qingdao, Shandong 266000, China (CHN)

DL 10192023

COPY

Willow Birch

QA APPROVED
TN09142023

Certificate of Analysis

Product Name: Papaverine HCL, USP | **Willow Birch Pharma Batch No: 08082300107**

CAS Number: 61-25-6 | **API Mfg: Recordati**

Mfg. Batch No: 22100468 | **Retest Date: 09/02/2027**

TESTS	SPECIFICATIONS	RESULTS
Description	White odorless crystalline powder	Complies
IR Spectrum Identification	Complies with the reference	Complies
UV Spectrum Identification	Complies	Complies
Chlorides Identification	Positive	Positive
Eur.Ph.Assay (on dried basis)	99.0 - 101.0 %	100.9%
USP Assay (on dried basis)	98.5 - 100.5 %	100.1%
Loss on drying	NMT 0.50 %	0.02%
HPLC E.P.Imp.B (PAPAVERINOL)	NMT 0.10 %	<0.05 %
HPLC E.P.Imp.C (DIHYDROPAPAV)	NMT 0.10 %	<0.05 %
HPLC E.P.Imp.D (PAPAVERALD)	NMT 0.10 %	<0.05 %
HPLC E.P.Imp.E (TETRAHYDROPAP)	NMT 0.10 %	<0.05 %

Invoice # 7696
Qty. Rcv'd 9 X 100gm
Date Rcv'd 08/14/2023
RPh Initials MT

DL 09/19/2023

QC COPY

Note: The above information is based on Recordati's manufacturing facility's Certificate of Analysis as well as testing performed by LGM Pharma for Willow Birch Pharma.

Manufacturer address: Campoverde Via Mediana Cisterna, 404011 Campoverde Di Aprilia, Italy

COPY
DL 10/12023

Willow Birch Pharma

HPLC E.P.Imp.F	NMT 0.10 %	<0.05 %
HPLC Each other impurity	NMT 0.10 %	<0.05 %
HPLC Total impurities	NMT 0.50 %	<0.05 %
Sulphated ash	NMT 0.10 %	0.01 %
pH (2% in water)	3.0 - 4.0	3.2
Clarity of water solution	Clear	Clear
Colour of water solution	< 6th level EP	Complies
Completeness of chloroform solut.		Complies
Readily carbonisable sub. (USP/IP)		Complies
Org.res.solv.Methanol	NMT 100 ppm	<32 ppm
Org.res.solv.Dimethylcarbonate	NMT 50 ppm	< 10 ppm
Particle size D(10%)	10 - 50 µm	35 µm
Particle size D(50%)	20 - 100 µm	83 µm
Particle size D(90%)	100 - 400 µm	136 µm
Bulk Density Loose	0.60 - 80 gr/ml	0.61 gr/ml
Bulk Density Tapped	0.70 - .090 gr/ml	0.71 gr/ml
HPLC E.P. IMP.A (NOSCAPINE)	Not applicable to our process	

Note: The above information is based on Recordati's manufacturing facility's Certificate of Analysis as well as testing performed by LGM Pharma for Willow Birch Pharma

Manufacturer address: Campoverde Via Mediana Cisterna, 404011 Campoverde Di Aprilia, Italy
Date of Manufacture by Recordati: 12/15/2021

Prepared By:
Date: 08/08/2023

Approved By: Tadavy
Date: 08/08/2023

Pharma Source

Invoice #_____
Qty. Rcv'd_____
Date Rcv'd_____
RPh Initials_____

Certificate of Analysis

Product	Testosterone Cypionate
Lot	23123R2-077
Expiration Date	04/29/2025
Compendium	USP

Manufacturer Information
Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
No. 302, Huzhuangtou, Sanhuangmiao, Zhenglu,
Tianning, Changzhou, Jiangsu, 213111, China

Manufacture Date	04/30/2022
Manufacturer Lot	C52-230401(M)

Test	Specification	Result
Appearance	White or almost white crystalline powder	White crystalline powder
Identification	IR spectrum of the sample should correspond to that of the working standard.	Complies
Melting point	98°C to 104°C	99.5°C to 100.5°C
Specific rotation	+85° to +92°	+91°
Loss on drying	0.5% Max	0.11%
Residue on ignition	0.2% Max	0.04%
Free cyclopentanepropionic acid	0.2% Max	0.12%
Related Substances		
Any impurity	0.8% Max	0.20%
Total impurities	1.6% Max	0.36%
Assay	97.0% ~ 103.0%	99.6%
Residual Solvents		
Ethyl acetate	5000ppm Max	127ppm
Methanol	3000ppm Max	Not detected
Ethanol	5000ppm Max	61ppm
Methylbenzene	890ppm Max	Not detected
Pyridine	200ppm Max	Not detected
Benzene	2ppm Max	Not detected

DL 07/21/2023
QA APPROVED

DL 10/19/2023
COPY

99.6% - 0.11%
99.49%
DL
07/26/2023

Per the manufacturer, the product conforms to USP-NF-2022 specifications.

The above test results are a direct transcription of the manufacturer's original Certificate of Analysis

Lot Testing

Pharma Source

Certificate of Analysis

Product	Testosterone Cypionate
Lot	23123R2-077
Expiration Date	04/29/2025
Compendium	USP

Manufacturer Information
Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
No. 302, Huzhuangtou, Sanhuangmiao, Zhenglu,
Tianning, Changzhou, Jiangsu, 213111, China

Manufacture Date	04/30/2022
Manufacturer Lot	C52-230401(M)

Test	Specification	Result
Infrared Identification <197A>	IR spectrum matches standard	IR spectrum matches standard
Bacterial Endotoxins <85>	Report	<0.01 EU/mg

Lot Tested By
Compounders International Analytical Laboratory
4760 Castleton Way
Castle Rock, CO 80109

Quality Release
Mike Maccarone

Release Date 05/19/23

STOKES
DUAL PRESSURE PRESS
MODEL
SERIAL
LOT
F. 4
F J STOKES CORPORATION

RED

Logged Formula Worksheet (detailed) LG1831811
9/13/2023 2:39:47 PM **FINALIZED**
Page 1

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

SILDENAFIL CITRATE 100 MG FASTSL

Tall Man

NIOSH Hazard ☐

Flavor: ORANGE
Quantity made: 100 TAB

Batch yield: 100.000
Qty remaining: 100.000

Schedule: L 129495
PCCA ID:
Route of admin: SUBLINGUAL

Active
Formula ID: 129495
Log ID: 1831811 ☑

Date made: 9/11/2023
Lot number: 09112023@32
Beyond use date: 3/9/2024 9:35 AM
180 days after compounding date

Pharmacist: KARI ANNE BERTHOLD
Technician: JOEL TODD
Misc. Note: PWDR
NDC1:

Pricing calculations from the log
Estimated price $10.25 as of
Time to make: 0

Picture

Description: WHITE SCORED TABLET ROUND
Packaging: OPAQUE CONTAINER
Equipment: MACHINE # PUNCH # COMPRESS AT 470 MG PER TABLET

Labeling: WEIGH/MIX: FINISH: YIELD: LOT VERIFICATION RPH CK:
Stability information: BEYOND USE DATE REF: THE BUD IS 180 DAYS ACCORDING TO USP 795 GUIDELINES: 21.10.80 FOI
Storage information: ROOM TEMPERATURE
Hazard codes:

Chemicals	NIOSH Hazard Schedule	Quantity used	QS (balance)
1 SILDENAFIL CITRATE POWDER	☐ L	10 GM	☐ 10.0 g

Lot #: 2302070166 Mfg: SMS LIFESC CAS: Stock: 121.27 NDC: 62991255603
Hazard code: Volume: Potency: Exp. date: 11/30/2027 QS amount: Whlsr: LETCO MEDICAL
ChemInvID: 10464
AWP: $0.00
Balance info: Purity: Tare: 0.0 g Percent off: 0% 10.0 g
Bar code checked: ☑ Each TAB contains 0.1 GM or 10%
NDC:

2 SL BASE W PHARMABURST #3 POWDER ☐ 36 GM ☐ 36.1 g

Lot #: 09112023@20 Mfg: STORE CAS: Stock: 22.4 NDC:
Hazard code: Volume: Potency: Exp. date: 3/9/2024 QS amount: Whlsr: STORE
ChemInvID: 10735
AWP: $0.00
Balance info: Purity: Tare: 0.2 g Percent off: 0.3% (over weight) 36.1 g
Bar code checked: ☐ Each TAB contains 0.36 GM or 36%
NDC:

3 STEARIC ACID NF POWDER ☐ 1 GM ☐ .002

Lot #: 194160E Mfg CAS: Stock: 498.0 NDC: 38779-1877-08
Hazard code: Volume: Potency: Exp. date: 7/31/2025 QS amount: Whlsr: MEDISCA
ChemInvID: 10704
AWP: $0.00
Balance info: Purity: Tare: 0.000 g 1.005 g Minimum Weight: 0.000 g
Bar code checked: ☑ Each TAB contains 0.01 GM or 1%
NDC:

(Added all GM & GMS: 47.00 All ML: 0.00) **Total ingredient cost**

Log Instructions & Notes

New Log Originally made as: 100 SILDENAFIL 100 MG FASTSL Formula ID: 129495
Calculated lot number: 09112023@32 Beyond use date: 3/9/2024
FORMULA INSTRUCTIONS:
By checking the boxes and writing you initials, you have indicated that you used the equipment specified and cleaned it after use. These initials further indicate that if the equipment was not visually clean before use, that you cleaned it before using it for compounding. Unless there's a date

Date entered: 9/11/2023 9:36:06 AM **Last modified:** 9/11/2023 10:11:54 AM **by:** JOEL
Checked by: _____ **Date:** ___/___/_____

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

SILDENAFIL CITRATE 100 MG FASTSL

Tall Man:

NIOSH Hazard ☐

Flavor: ORANGE
Quantity made: 100 TAB
Batch yield: 100.000
Qty remaining: 100.000
Schedule: L 129495
PCCA ID:
Route of admin: SUBLINGUAL
Active
Formula ID: 129495
Log ID: 1831611 ☑

next to your initials, it is assumed that compounding and related cleaning occurred on the date appearing on the logged formula worksheet in the "date made" field.

Principles of Geometric Dilution:
Geometric Dilution is the process by which a homogenous mixture or even distribution of two or more substances is achieved. When using this method, the smallest quantity of active ingredient is mixed thoroughly with an equal volume of the diluent in a mortar and pestle. More diluent (excipient) is added in amounts equal to the volume of the mixture in the mortar and pestle. This process is repeated until all of the diluent (excipient) is incorporated in the mixture. This method, though time consuming, will create a homogenous mixture or smooth dispersion of the drug and diluent (excipient).

Calculation for 100 tablets:
Sildenafil: (10,000mg/1000) = 10 gm

Directions for Compounding:
1. Determine batch size and enter into quantity field on log formula worksheet.
2. Scan and accurately weigh ingredients.
    Invomatic:
        Place weighed powder in appropriate sized container for the batch. (Not more than 70% of powder for container volume)
        Twist top of container tightly and load into Invomatic Blender.
        Mix a 75% speed for 5 minutes.

    Mortar and Pestle:
        If needed, blend powders using geometric dilution prior to sieving into Invomatic Blender container.

3. Visually inspect for thorough blend.
4. Print three batch labels and affix one to log formula worksheet, one to appropriate size bag and one to final tablet container.
5. Weigh final blend and record on log formula worksheet.
6. Transfer labeled bag of powder, log formula worksheet and final tablet container to tablet press room.
7. Select proper tablet press and tooling as noted on log formula worksheet.
8. Set tablet press for desired tablet weight.
9. Periodically weigh a random tablet during batch process and adjust weight setting as necessary.
10. Periodically check tablets for appearance.

Date entered: 9/11/2023 9:36:06 AM Last modified: 9/11/2023 10:11:54 AM by: JOEL
Checked by: _____ Date: ___/___/____

Logged Formula Worksheet (detailed)
9/13/2023 2:39:47 PM **FINALIZED**
Page 3

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

SILDENAFIL CITRATE 100 MG FASTSL

Tall Man:

NIOSH Hazard ☐

Flavor: ORANGE
Quantity made: 100 TAB
Batch yield: 100.000
Qty remaining: 100.000
Schedule: L 129495
PCCA ID:
Route of admin: SUBLINGUAL
Active ☑
Formula ID: 129495
Log ID: 1831811

11. Calculate yield and record on log formula worksheet.
12. Bottle batch into labeled and final tablet container and transfer to metal detector.
13. Run batch through metal detector, rebottle and transfer to dispensing along with log formula worksheet.

Quality Control:
JBT Powder accurately weighed
JBT Ingredients thoroughly blended to a uniform mixture.

Technician Initials JBT

JBT Tablet within weight range
JBT Tablet appearance (solid, clean)
JBT Passed metal detection

Technician Initials JBT

Storage and Beyond Use Date:
Store in at room temperature.
Beyond Use Date Ref: The BUD is 180 days according to USP 795 Guidelines: 21.10.80 for Solid formulations

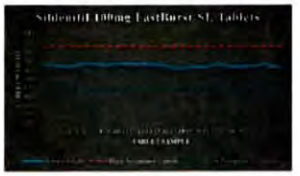
Date entered: 9/11/2023 9:36:06 AM Last modified: 9/11/2023 10:11:54 AM by: JOEL
Checked by: _____ Date: __/__/____

Sildenafil 100mg FastBurst SL Tablet — Production date: 9/11/2023

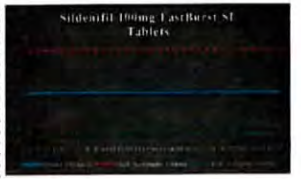
Lot: [illegible] — Expiration date: 3/9/2024

Quantity made: 498/500

Tablet weight	High Accep.	Low Acceptance Criteria
475	517	423
475	517	423
475	517	423
475	517	423
475	517	423
478	517	423
478	517	423
475	517	423
475	517	423
478	517	423
475	517	423
479	517	423
475	517	423
475	517	423
475	517	423
488	517	423
480	517	423
480	517	423
472	517	423
472	517	423
475	517	423
475	517	423
473	517	423
475	517	423
475	517	423
475	517	423
475	517	423
479	517	423
478	517	423
490	517	423
494.3		



Tablet	Tbs	High Accep	Low Acceptance Criteria
	3.162	3.4815	2.8485
	3.166	3.4815	2.8485
	3.165	3.4815	2.8485
	3.167	3.4815	2.8485
	3.169	3.4815	2.8485
	3.164	3.4815	2.8485
	3.164	3.4815	2.8485
	3.169	3.4815	2.8485
	3.169	3.4815	2.8485
	3.165	3.4815	2.8485
	3.167	3.4815	2.8485
	3.166	3.4815	2.8485
	3.167	3.4815	2.8485
	3.168	3.4815	2.8485
	3.166	3.4815	2.8485
	3.167	3.4815	2.8485
	3.165	3.4815	2.8485
	3.164	3.4815	2.8485
	3.163	3.4815	2.8485
	3.166	3.4815	2.8485
	3.169	3.4815	2.8485
	3.168	3.4815	2.8485
	3.169	3.4815	2.8485
	3.169	3.4815	2.8485
	3.169	3.4815	2.8485
	3.168	3.4815	2.8485
	3.164	3.4815	2.8485
	3.165	3.4815	2.8485
	3.166	3.4815	2.8485
	3.166	3.4815	2.8485



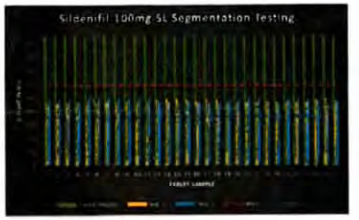
High: 517
Low: 423

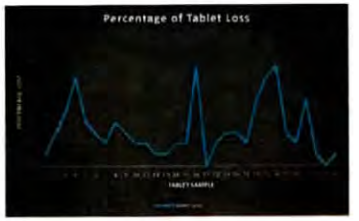
Segmentation test

Tablet	Tablet Weight	Seg. 1	Seg. 2	High	Low
1	475	260	244	293.75	176.25
2	475	229	245	293.75	176.25
3	473	228	245	293.75	176.25
4	473	231	234	293.75	176.25
5	475	219	242	293.75	176.25
6	478	230	245	293.75	176.25
7	478	230	246	293.75	176.25
8	475	229	242	293.75	176.25
9	475	228	243	293.75	176.25
10	476	233	243	293.75	176.25
11	478	232	244	293.75	176.25
12	475	240	234	293.75	176.25
13	479	243	235	293.75	176.25
14	475	242	232	293.75	176.25
15	475	240	239	293.75	176.25
16	477	235	233	293.75	176.25
17	488	240	228	293.75	176.25
18	485	241	228	293.75	176.25
19	470	230	237	293.75	176.25
20	472	229	240	293.75	176.25
21	477	229	241	293.75	176.25
22	475	228	241	293.75	176.25
23	479	237	235	293.75	176.25
24	472	232	231	293.75	176.25
25	473	230	240	293.75	176.25
26	473	228	244	293.75	176.25
27	473	229	234	293.75	176.25
28	478	240	238	293.75	176.25
29	473	244	229	293.75	176.25
30	470	233	238	293.75	176.25

Average Segment Weight: 235.4667
High Acceptance Criteria: 293.75
Low Acceptance Criteria: 176.25

Tablet	Tablet weight	Segmenter Tablet Lost
1	475	474
2	475	473
3	478	468
4	473	465
5	475	473
6	478	475
7	478	479
8	475	473
9	475	473
10	478	476
11	478	476
12	475	474
13	479	478
14	475	473
15	475	475
16	475	465
17	488	488
18	485	487
19	470	467
20	472	468
21	477	470
22	475	469
23	479	467
24	472	466
25	473	470
26	473	471
27	473	467
28	478	476
29	473	473
30	470	469





R&D

Logged Formula Worksheet (detailed)
9/13/2023 2:40:52 PM **FINALIZED**
Page 1

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

TADALAFIL 20 MG FASTSL

Tall Man:

NIOSH Hazard ☐

Flavor: ORANGE
Quantity made: 100 TAB

Batch yield: 100.000
Qty remaining: 100.000

Schedule: L 129503
PCCA ID:
Route of admin: SUBLINGUAL

Active ☑
Formula ID: 129503
Log ID: 1831830

Date made: 9/11/2023
Lot number: 09112023@48
Beyond use date: 3/9/2024 10:44 AM
180 days after compounding date
Pharmacist: KARI ANNE BERTHOLD
Technician: JOEL TODD
Misc. Note: PWDR
NDC1:

Pricing calculations from the log
Estimated price $10.25 as of
Time to make: 0

Picture

Description: WHITE SCORED TABLET ROUND
Packaging: OPAQUE CONTAINER
Equipment: MACHINE # PUNCH # COMPRESS AT 230 MG PER TABLET (-/+ 223-237)

Labeling: WEIGH/MIX: FINISH: YIELD: 21/100 LOT VERIFICATION RPH CK: 09/13/23
Stability information: BEYOND USE DATE REF: THE BUD IS 180 DAYS ACCORDING TO USP 795 GUIDELINES: 21.10.80 FO
Storage information: ROOM TEMPERATURE
Hazard codes:

Chemicals	NIOSH Hazard Schedule	Quantity used	QS (balance)
1 TADALAFIL USP POWDER	☐ L	2 GM	☐ 2.002

CAS: Stock: 96 NDC: 62991312804
Lot #: 2210130025 Mfg: SRINI PHAR Exp. date: 11/30/2027 Whlsr: LETCO
Hazard code: Volume: Potency: QS amount: CheminvID: 10444
AWP: $0.00
Purity:
Balance info: Tare: 0.000 g
2.000 g Minimum Weight: 0.000 g
Bar code checked: ☐ Each TAB contains 0.02 GM or 2%
NDC:

2 SL BASE W PHARMABURST #3 POWDER	☐	20.8 GM	☐ 20.8 g

CAS: Stock: 22.4 NDC:
Lot #: 09112023@20 Mfg: STORE Exp. date: 3/9/2024 Whlsr: STORE
Hazard code: Volume: Potency: QS amount: CheminvID: 10735
AWP: $0.00
Purity:
Balance info: Tare: 0.0 g
Percent off: 0% 20.8 g
Bar code checked: ☐ Each TAB contains 0.208 GM or 20.8%
NDC:

3 STEARIC ACID NF POWDER	☐	0.2 GM	☐ 0.2004

CAS Stock: 498.6 NDC: 38779-1877-08
Lot #: 194160E Mfg: Exp. date: 7/31/2025 Whlsr: MEDISCA
Hazard code: Volume: Potency: QS amount: CheminvID: 10704
AWP: $0.00
Purity:
Balance info: Tare: 0.000 g
0.201 g Minimum Weight: 0.000 g
Bar code checked: ☑ Each TAB contains 0.002 GM or 0.2%
NDC:

(Added all GM & GMS: 23.00 All ML: 0.00) **Total ingredient cost**

Log Instructions & Notes

New Log Originally made as: 100 TADALAFIL 20 MG FASTSL Formula ID: 129503
Calculated lot number: 09112023@48 Beyond use date: 3/9/2024
FORMULA INSTRUCTIONS:
By checking the boxes and writing you initials, you have indicated that you used the equipment specified and cleaned it after use. These initials further indicate that if the equipment was not visually clean before use, that you cleaned it before using it for compounding. Unless there's a date

Date entered: 9/11/2023 10:45:06 AM **Last modified:** 9/13/2023 2:41:32 PM **by:** JOEL
Checked by: _____ **Date:** ___/___/_____

① 79 tablets leftover after sample taken

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

TADALAFIL 20 MG FASTSL

Tall Man:

NIOSH Hazard ☐

Flavor: ORANGE
Quantity made: 100 TAB
Batch yield: 100.000
Qty remaining: 100.000
Schedule: L 129503
PCCA ID:
Route of admin: SUBLINGUAL
Active ☑
Formula ID: 129503
Log ID: 1631639

next to your initials, it is assumed that compounding and related cleaning occurred on the date appearing on the logged formula worksheet in the "date made" field.

Principles of Geometric Dilution:
Geometric Dilution is the process by which a homogenous mixture or even distribution of two or more substances is achieved. When using this method, the smallest quantity of active ingredient is mixed thoroughly with an equal volume of the diluent in a mortar and pestle. More diluent (excipient) is added in amounts equal to the volume of the mixture in the mortar and pestle. This process is repeated until all of the diluent (excipient) is incorporated in the mixture. This method, though time consuming, will create a homogenous mixture or smooth dispersion of the drug and diluent (excipient).

Calculation for 100 tablets:
Tadalafil: (2,000mg/1000) = 2 gm

Directions for Compounding:
1. Determine batch size and enter into quantity field on log formula worksheet.
2. Scan and accurately weigh ingredients and equipment
   Invomatic:
      Place weighed powder in appropriate sized container for the batch. (Not more than 70% of powder for container volume)
      Twist top of container tightly and load into Invomatic Blender.
      Mix a 75% speed for 5 minutes.

   Mortar and Pestle:
      If needed, blend powders using geometric dilution prior to sieving into Invomatic Blender container.
   V-Blender: Use for big batches and thyroids:
      Place all powder ingredients in the blender except the stearic acid. Mix for __ minutes. Open container and add the stearic acid. Mix for __ minutes.
3. Visually inspect for thorough blend.
4. Print three batch labels and affix one to log formula worksheet, one to appropriate size bag and one to final tablet container.
5. Weigh final blend and record on log formula worksheet.
6. Transfer labeled bag of powder, log formula worksheet and final tablet container to tablet press room.

Instructions for Tablet Press:

Logged Formula Worksheet (detailed)
9/13/2023 2:40:52 PM **FINALIZED**
Page 3

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

TADALAFIL 20 MG FASTSL

Tell Man:

Flavor: ORANGE
Quantity made: 100 TAB

Batch yield: 100.000
Qty remaining: 100.000

Schedule: L 129503
PCCA ID:
Route of admin: SUBLINGUAL

NIOSH Hazard ☐
Active
Formula ID: 129503 ☑
Log ID: 1831830

7. Select proper tablet press and tooling as noted on log formula worksheet.
8. Set tablet press for desired tablet weight.

Load powder into tablet press hopper, set the tablet weight and hardness. Once reached optimal hardness, record the hardness of two tablets here. #1 N/A [illegible] #2 ____

9. Periodically weigh a random tablet during batch process and adjust weight setting as necessary.
10. Periodically check tablets for appearence.

Record tablet weights below, record 5 tablet weights for every 200 tablets up to 1000 tablets. Over 1000 tablets use quality form.

228 mg 226 mg 227 mg 230 mg 228 mg (2-200 tablets) See attached form for additional information [illegible]

___ mg ___ mg___ mg___ mg___ mg (200-400 tablets)

___ mg ___ mg___ mg___ mg___ mg (400-600 tablets)

___ mg N/A [illegible] mg___ mg___ mg___ mg (600-800 tablets)

___ mg ___ mg___ mg___ mg___ mg (800-1000 tablets)

*if the weight of the tablets are out of range and adjusting machine doesn't help - immediately contact the quality department to verify the formulation.

11. Discard out of range tablets from the end of the run and remove excess powder from tablets.
12. Place empty labeled container on balance and tare, add finished tablets to conteiner and weigh.
11. Calculate yield and record on log formula worksheet.
12. Transfer to metal detector.
13. Run batch through metal detector, rebottle and transfer to dispensing along with log formula worksheet.

Quality Control:
JOT Powder accurately weighed
JOT Ingredients thoroughly blended to a uniform mixture.
JOT Ingredients mixed using appropriate method.

Technician Initials JOT

JOT Tablet within weight range
JOT Tablet appearance (solid, clean)
JOT Passed metal detection.
N/A [illegible] Passed tablet hardness parameters

Technician Initials JOT

Date entered: 9/11/2023 10:45:06 AM Last modified: 9/13/2023 2:41:32 PM by: JOEL
Checked by: _____ Date: ___/___/___

Logged Formula Worksheet (detailed)
9/13/2023 2:40:52 PM **FINALIZED** LG1831830
Page 4

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

TADALAFIL 20 MG FASTSL

Tall Man:

Flavor: ORANGE
Quantity made: 100 TAB

Batch yield: 100.000
Qty remaining: 100.000

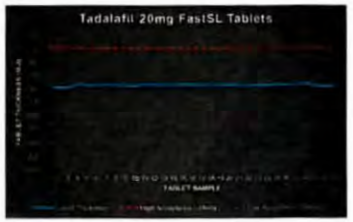
Schedule: L 129503
PCCA ID:
Route of admin: SUBLINGUAL

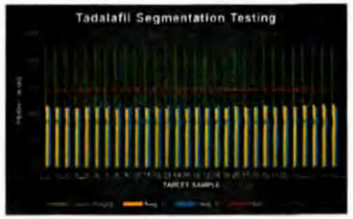
NIOSH Hazard ☐
Active
Formula ID: 129503 ☑
Log ID: 1831830

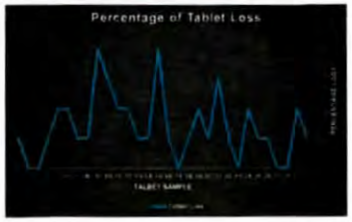
Storage and Beyond Use Date:
Store in at room temperature in a light resistant vial
Beyond Use Date Ref: The BUD is 180 days according to USP 795 Guidelines: 21.10.80 for Solid formulations

Date entered: 9/11/2023 10:45:06 AM **Last modified:** 9/13/2023 2:41:32 PM **by:** JOEL
Checked by: _____ **Date:** ___/___/_____

Tadalafil 20mg FastSL Tablets
TABLET SAMPLE


Tadalafil 20mg FastSL Tablets
TABLET SAMPLE


Tadalafil Segmentation Testing
TABLET SAMPLE


Percentage of Tablet Loss
TABLET SAMPLE

Pharmacy Name: Women's International Pharmacy, Inc.

Pharmacy Address: 12012 N. 111th Ave., Youngtown, AZ 85363

NABP Facility e-Profile ID: 758539

VPP Inspection Date: 10/19/2023

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	8	16.00	The most recent inspection by the Arizona State Board of Pharmacy was on 3/29/2023, not 5/1/2024.	In compliance at time of inspection.	N	
Clarification or Further Explanation	9	28.02	E-scripts for controls are printed out for filing but the original is maintained electronically as allowed by state and federal law.	In compliance at time of inspection.	N	
Clarification or Further Explanation	9	28.04	There are systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed. The answer to this question should be yes as evidenced by the inspector's comments in the notes field.	In compliance at time of inspection.	N	
Clarification or Further Explanation	11, 43	37.05, 12.03	While Women's International Pharmacy, Inc. ("WIP") compounds with hazardous *drugs* as defined by NIOSH/USP 800, we do not routinely compound/handle hazardous *waste* defined by EPA/RCRA. WIP follows federal, state and local laws for hazardous waste disposal including 40 CFR 261.7 Residues of Hazardous Waste in Empty Containers. If a container is not empty as defined by federal law, WIP utilizes 123 Compliant Logistics for disposal.	In compliance at time of inspection.	Y	Attachment 1 - 123 Compliant Logistics destruction report
Clarification or Further Explanation	13	47.04-47.10	See attached for DSCSA SOP.	In compliance at time of inspection.	Y	Attachment 2 - SOP 14.00.06 Drug Supply Chain Security Act (DSCSA) Procedure
Clarification or Further Explanation	16, 23, 40	67.01, 1.01, 1.01	Women's International Pharmacy, Inc. ("WIP") staff collect allergy, condition and other medication information from patients at every point of contact. Staff have been trained to WI-1.00.10-20 Work Instruction for LifeFile – Contact the Patient and Customer Experience Training Series: Onboarding New Patients. All staff will complete retraining before November 15, 2023 to emphasize the importance of obtaining all information necessary for pharmacists to perform DUR. Additionally, WIP sends an email to each patient annually during their birthday month asking them to update their profile, including allergies, conditions and other medications so WIP has the most up-to-date information on file.	11/15/2023	Y	Attachment 3 - WI 1.00.10-20 Work Instruction for LifeFile – Contact The Patient, Attachment 4 - Customer Experience Training Series - Onboarding New Patients
Clarification or Further Explanation	17	71.00	Packing materials are regularly validated using data loggers placed in prescription vials and packed just like the suppositories were (in vial directly against an ice pack).	In compliance at time of inspection.	N	
Clarification or Further Explanation	22	93.00	Consumer surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. The answer to this question should be yes as evidenced by the inspector's comments in the notes field.	In compliance at time of inspection.	N	

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name: Women's International Pharmacy, Inc.

Pharmacy Address: 12012 N. 111th Ave., Youngtown, AZ 85363

NABP Facility e-Profile ID: 758539

VPP Inspection Date: 10/19/2023

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	34	61.08	Order of mixing has been added to master formulation record.	11/2/2023	Y	Attachment 5 - Master Formulation Record
Clarification or Further Explanation	42	9.01	If WIP does not have testing to justify the use of extended BUDs, USP guidelines are used.	In compliance at time of inspection.	N	
Updates/New SOPs or P&Ps	56	79.00	Effective November 1, 2023, with the implementation of updated 797 sterile compounding standards, designated persons with direct oversight of compounding personnel will not verify sterile compounding procedures or prescriptions until they have completed garbing competency, media fill with post gloved fingertip testing and surface sampling with passing results at least every 12 months. If compounding, these competency assessments will be performed every 3 months.	11/1/2023	N	Attachment 6 - SOP 7.00.10 Media Fill Trial for High-Risk Level CSPs, Attachment 7 - SOP 7.00.01 Hand Hygiene and Garbing Hazardous Sterile Areas, Attachment 8 - SOP 7.00.02 Hand Hygiene and Garbing Nonhazardous Sterile Area

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Attachment 1

123 Compliant Logistics

CUSTOMER INFORMATION					
Facility Name	Women's International Pharmacy				
DEA Registrant	FW0066856				
Service Address	12012 North 111th Ave.				
City	Youngtown, AZ	**State**	AZ	**Zip**	85363-1339

# of Controlled Containers	# of Non-Controlled Containers	Total Number of Containers
(1) 12.0 CBS	(6) 63.0 LBS	(7) 75.0 CBS

Susan Mogen
Customer Print Name

X Susan L. Mogen
Customer Signature

For Office Use Only:

7-19-23 — Receiving Date
10 AM — Receiving Time
123 CL Employee Signature

Non-Controlled Compound Inventory

9-19-23

DEA REGISTRANT **Women's International Pharmacy**
Address **12012 N 111th Ave**
City **Youngtown** State **AZ** ZIP **85363**
Contact **Sue Mogen** Phone **623-214-7700 ext 1531**
DEA **FW0066856** Expiration Date **05-31-24** State Permit **Y008610**

	NDC	DRUG NAME	FORM	# OF CONTAINERS	QTY
1	02400003642	P-T3 (LIOTHYRONINE) 10 MCG CAPSULES	OLIVE OIL	1	700 Cap
2	02400140760	P-T3 23 MCG/T4 135 MCG CAPSULES	OLIVE OIL	1	60 Cap
3	02400013832	P-T4 (LEVOTHYROXINE) 15 MCG CAPSULES	OLIVE OIL	1	60 Cap
4	02400061001	P-T4 (LEVOTHYROXINE) 110 MCG CAPSULES	OLIVE OIL	1	45 Cap
5	02400147409	P-T3 9 MCG/T4 90 MCG CAPSULES	OLIVE OIL	1	60 Cap
6	73209-0002-02	Estriol	powder	2	1000 gm
7	38779-0567-08	Microcrystalline Cellulose	powder	1	500 g
8	Lot 07032023cH	Menthol anne Mosgate / Mucoat 5/35 mg	powder triturate	1	5 g
9	00000 0000-01	Cream flavor all natural	powder	1	434.5 g
10	LG 1810916	B24 Progesterone 100 mg/gm cream	cream	1	75
11	LG 1811968	E3/E2 3/1.5 mg/gm	cream	1	30 gm
12	LG 1811483	E3/E2 Orange Sp. 0.1 ml	oral susp	1	10 ml
13	LG 1811944	Naltrexone HCL 1 mg/0.1 ml	glycerin susp	2	100 ml
14	LG 1810603	E3/E2 1.2/0.4 mg/gm	cream	1	35 gm
15	LG 1810746	E2/P4 3200 mg/gm	cream	1	30 gm
16	LG 1810640	E2 2/P4 100 mg/gm	cream	1	90 gm
17	LG 1810855	E3/E2 1.6/0.4 mg/gm	cream	1	40 gm
18	LG 1811761	Liothyronine/Levothyroxine 35/110 mcg	oral cap	1	90 cap
19	LG 1810432	Estradiol 2 mg/gm	cream	2	45 g
20	LG 1810453	E3/E2/P4 0.8/0.2/100 mg/gm	cream	2	45 g

Attachment 2

Belmar PHARMA SOLUTIONS	Document Number: SOP 14.00.06	CHAPTER 14: Compliance	Version 1.0
	Document Title: Drug Supply Chain Security Act (DSCSA) Procedure (503A-APS, BP-CO, BP-FL, WIP-AZ, WIP-WI)		Document Status Effective
			Effective Date 05/31/2023
Author: Michelle Violi		Authorized By: Kristen Youngdahl	

1.0 PURPOSE

The purpose of this procedure is to provide guidance on proper procedure of identifying and investigating suspicious manufactured drug products.

Drug Supply Chain Security Act is an act enacted by Congress and enforced by the FDA to help protect consumers from exposure to manufactured drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. 503A facilities are responsible for receiving the transaction statement (T3) from the supplier and investigating if the product appears suspicious or illegitimate. The T3 includes the following three documents: the transaction history (TH), the transaction information (TI), and the transaction statement.

2.0 SCOPE

The scope of this procedure applies to all 503A facilities purchasing or compounding with manufactured drug product (APIs excluded) and dispensing manufactured drug product to a patient.

3.0 RESPONSIBILITY

3.1 It is the responsibility of the pharmacist-in-charge and/or the quality unit to assure that all personnel involved in ordering, reviewing, and receiving manufactured drug products are trained in the requirements of this procedure.

3.2 It is the responsibility of the PIC to perform any necessary investigations and make the final determination if reporting to FDA is necessary in consultation with the Director of Compliance.

3.3 It is the responsibility of all personnel at Belmar Pharma Solutions 503A facilities to comply with this procedure.

3.4 Supplier Quality Manager will verify suppliers have valid licensure using FDA database prior to placing an order.

4.0 DEFINITIONS

Terms and definitions are available in Corporate Glossary.

5.0 MATERIALS AND EQUIPMENT

5.1 Manufactured drug products

5.2 3T Database

6.0 GENERAL INFORMATION

6.1 SUSPECT PRODUCT—The term "suspect product" means a product for which there is reason to believe that such product: (A) is potentially counterfeit, diverted, or stolen; (B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is potentially the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans. (per Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry as published by FDA)

6.2 ILLEGITIMATE PRODUCT—The term "illegitimate product" means a product for which credible evidence shows that the product: (A) is counterfeit, diverted, or stolen; (B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans; (C) is the subject of a fraudulent transaction; or (D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to

humans. (per Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act Guidance for Industry as published by FDA)

6.3 Frequency

6.3.1 As needed, whenever purchasing and receiving manufactured drug products.

7.0 PROCESS MAP

8.0 PROCEDURE

8.1 Belmar Pharma Solutions (BPS) 503A facilities will only purchase from suppliers authorized by the Supplier Quality Manager.

8.2 BPS 503A facilities will not accept ownership of a manufactured drug product unless the transaction history, transaction information and a transaction statement (T3) is provided by the previous owner.

8.3 If BPS 503A facilities transfers ownership of a manufactured drug product, BPS will provide the subsequent owner with T3 information.

8.3.1 T3 information is not required to be provided to the subsequent owner for the following:

8.3.1.1 Dispensing to a patient

8.3.1.2 Returns to the manufacturer or to a reverse distributor for destruction

8.3.1.3 Sale to a pharmacy to fulfill a specific patient need

8.3.1.4 Transfer to a pharmacy under the same ownership. BPS has the following pharmacies under the same ownership:

8.3.1.4.1 APS

8.3.1.4.2 Belmar Pharmacy – Colorado (BP-CO)

8.3.1.4.3 Belmar Pharmacy – Florida (BP-FL)

8.3.1.4.4 Custom Rx

8.3.1.4.5 MedQuest

8.3.1.4.6 Pharmacy Solutions

8.3.1.4.7 Women's International Pharmacy – Arizona (WIP-AZ)

8.3.1.4.8 Women's International Pharmacy – Wisconsin (WIP-WI)

8.4 BPS will engage in transactions involving a manufactured drug product only if such product is encoded with a product identifier.

8.5 BPS will maintain access to T3 information for 6 years following the transaction.

8.6 BPS may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the T3 information on behalf of BPS. BPS will maintain a copy of the written agreement.

8.7 Suspect Manufactured Drug Product

8.7.1 BPS will capture T3 information as necessary to investigate a suspect product.

8.7.2 If BPS determines they are in possession of a suspect product, they will:

8.7.2.1 Quarantine the product.

8.7.2.2 Promptly conduct an investigation in coordination with suppliers to determine whether the product is illegitimate.

8.8 Investigation

8.8.1 BPS will verify whether the lot number of the suspect manufactured drug product corresponds with the lot number for such product.

8.8.2 BPS will verify that the manufactured drug product identifier of at least 3 packages or 10% (whichever is greater) of the suspect product corresponds with the product identifier for such product.

8.8.3 BPS will validate any T3 information in their possession.

8.8.4 BPS will perform other investigation as necessary to determine whether the manufactured drug product is an illegitimate product.

8.9 Cleared Product

8.9.1 If BPS determines that the suspect manufactured drug product is not illegitimate, BPS will notify the FDA, if applicable, of such determination and the manufactured drug product may be distributed or dispensed.

8.9.1.1 After consultation with the Director of Compliance, click on the link to fill out form. Notify FDA of Illegitimate Products | FDA

8.10 Illegitimate Manufactured Drug Product

8.10.1 If BPS, in coordination with the manufacturer, determine that the manufactured drug product is an illegitimate product, BPS will dispose of the product.

8.10.2 BPS will take reasonable and appropriate steps to assist a supplier in disposing of the product.

8.10.3 BPS will retain a sample of the product for future analysis by the manufacturer or the FDA upon request.

8.10.4 BPS will notify the FDA and all immediate suppliers that they have reason to believe they may have received an illegitimate manufactured drug product. The notification must be made no later than 24 hours after making such determination. After consultation with the Director of Compliance, click on the link to fill out form. Notify FDA of Illegitimate Products | FDA

8.10.4.1 If BPS, in consultation with the FDA, determine that a notification is no longer necessary, BPS will promptly notify immediate suppliers (as notified above) that the notification has been terminated.

8.10.5 If BPS receives notification from the FDA or a supplier that a determination has been made that a manufactured drug product is illegitimate, BPS will follow all steps as described above under sections 8.8 and 8.9.

9.0 FORM BACKUP USAGE

If the Pestle system is not available, obtain a paper hardcopy of Pestle Tasks from site "Library of Backup forms", maintained by site Quality units.

10.0 REFERENCES

- Pestle Task – Read and Understand

11.0 ATTACHMENTS

Not applicable

12.0 HISTORY

Version Number	Date Effective	Description of Change	Change Control Number / Justification
1.0	05/31/2023	New SOP for corporate Belmar Pharma 503A facilities to describe the process for DSCSA.	CCCN23-10

Attachment 3

Belmar PHARMA SOLUTIONS	Document Number: WI1.00.10-20	CHAPTER 1: Policies and Procedures	Version: 1.0
	Document Title: Work Instruction for LifeFile – Contact The Patient (CTP) (503A – BP, WIP-AZ, WIP-WI)		Document Status: Effective
			Effective Date: 02/17/2023
Author: Julie Brown, Gina Boche		Authorized By: Kristen Youngdahl	

1.0 PURPOSE

The purpose of this work instruction is to detail the steps of contacting a patient about a new prescription or a change in a prescription before processing orders in the LifeFile dispensing system.

2.0 SCOPE

The scope of this procedure applies to all Customer Experience Center (CXC) staff and all pharmacists.

3.0 RESPONSIBILITY

3.1 The Director of Customer Experience Operations shall supervise this procedure and update the procedure as LifeFile order processing changes and develops.

3.2 The Pharmacist-in-charge (PIC)'s and Operations Managers at all Belmar Pharma Fulfillment sites are responsible for implementing the order processing standard.

4.0 DEFINITIONS

Terms and definitions are available in Corporate Glossary.

5.0 MATERIALS AND EQUIPMENT

5.1 LifeFile

6.0 GENERAL INFORMATION

6.1 Background

6.1.1 See standard operating procedure (SOP) 1.00.10 General LifeFile for the overall description of LifeFile dispensing software.

6.2 Required Training

6.2.1 Read and Understand SOP 1.00.10 and this work instruction.

6.2.2 CXC Pharmacists and Technicians must complete a training checklist for each process until they are deemed a proficient performer by the supervisor. See SOP Customer Service Training.

6.3 Frequency

6.3.1 As prescriptions are waiting to be processed with customer approval and/or information.

7.0 PROCEDURE

7.1 When to call/text the patient:

7.1.1 A patient should be contacted regarding a new prescription if the following criteria exist:

7.1.1.1 It is a New Patient (see New Patient Checklist).

7.1.1.2 If there is a change for a new prescription where it differs in drug, dose, dosage form, sig, or quantity, or if more than 14 days until the next expected Fill Date.

7.1.2 Prescriptions in the contact the patient (CTP) buckets require patient contact.

7.1.2.1 This was determined based on the order memo selected at populating (See Memos, Notes and Activities).

7.1.2.2 Orders enter the CTP bucket workflow from the CS bucket (See Managing the CS Bucket).

7.2 Patient Contact Workflow

7.2.1 CTP 1

7.2.1.1 The CTP 1 bucket does not need to be monitored. Patients receive an automated email and text at this step when the order is moved into the bucket.

7.2.1.2 After 8 business hours, the order will move from CTP 1 to CTP 2.

7.2.2 CTP 2

7.2.2.1 This bucket may need to be monitored. Orders in the CTP 2 bucket require a manual phone call by a technician as the second attempt.

7.2.2.2 This bucket may contain automated outbound calling technology and then this bucket will not need to be monitored. An automated call will go out to the patient with an automated recording to contact us or automated voicemail message will be left for the patient. The patient can also press 1 to be redirected back to the pharmacy tech line.

7.2.2.3 After 24 business hours, the order will flow from CTP 2 to Profiled when the manual in CTP 2. After 8 business hours, the order will flow from CTP 2 to Profiled when the outbound calls are automated.

7.3 CTP Standard Practices

7.3.1 Multiple order memos include CTP (see Memos, Notes and Activities). These, and the NEW PT memo, all require patient contact.

7.3.2 Orders with the CTP ASAP order memos should be prioritized at CTP.

7.3.2.1 If the order has an elevated priority status, in most cases the priority should be changed back to normal before going to Complete Processing. CTP ASAP means the call should be prioritized, but not necessarily the compounding or fulfillment.

7.3.2.1.1 If the compounding or fulfillment needs to be expedited, the lot request will be STAT or URGENT if the order is processed in these statuses. Documentation in the form of a sticky or addition to the memo is needed as to why.

7.3.2.2 The order should be dipped into CTP 1, Submit and Edit, and then immediately moved to CTP 2.

7.3.3 All CTP calls should verify the patient information, shipping, and billing and the offer to talk to a pharmacist (See General Order Processing).

7.3.4 If the patient is not ready to fill the prescription, the order should be moved to status Profiled Order. A sticky note is handy as to why.

7.3.5 If it is too early to fill, the order can be moved to Future Orders and scheduled to move back to CS on a certain date.

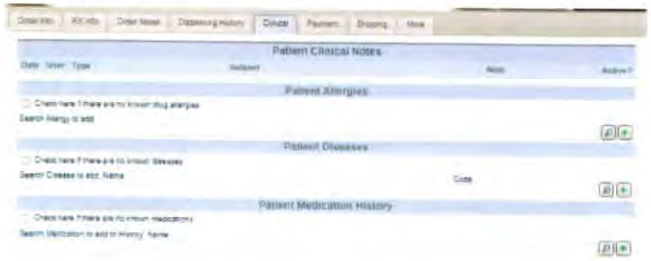
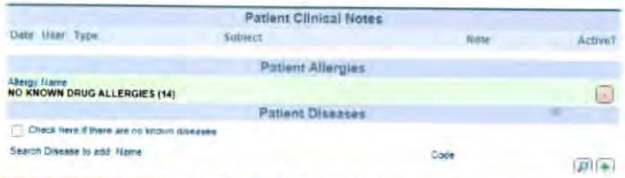
7.3.6 If the patient cannot be reached a message should be left to contact the pharmacy back and the order should be moved to Profiled Order. If it is a manual call and you leave a message, leave a note after the memo (Ex. LM/GB 1/1/23). Automated calls are timestamped in the Order Notes tab.

7.4 New Patient Checklist

7.4.1 A new patient will require some extra time and communication. An order in the CS Bucket (See managing the CS Bucket) that has the memo NEW PT, will be marked as urgent status, sent to CTP1, submit/edit, and immediately sent to CTP 2.

7.4.1.1 When the order is processed, the priority should be changed back to Normal.

New Patient Call Check List

- ☐ Introduce yourself, example: "Thank you for calling Belmar Pharmacy, this is _____, how can I help you?"
- ☐ Name and spelling.
- ☐ Date of Birth
- ☐ Address- let them tell you.
- ☐ Cell phone for text message notifications, order status, and refill reminders.
- ☐ Email for tracking, receipts, and order status.
- ☐ Any known drug/food allergies, diseases, or medical conditions they would like us to make note of in the clinical tab. The boxes must be checked if there are no known allergies, diseases or medical conditions. Ask the patient about other medications they are taking and input as necessary.
  - 
  - 

  - A Patient Priority Note should also be made for any severe allergies.
  - If there is anything severe, the call should be passed to a pharmacist and the pharmacist should document reactions.
- ☐ Has the patient ever had a prescription compounded before?

- ☐ Go over prescription(s) details with patient.
- ☐ Explain the cost as the Rx is written.
- ☐ How much would the patient like to fill (1 mo., 2 mo., 3 mo.?) Discuss price for higher quantities and potential price breaks. Except for controls, then you can dispense only what is written or less.
- ☐ Shipping options (free 2-day) and compounding time (3-5 days after payment).
- ☐ For refills, call us two weeks before your prescription runs out, so we have time to compound your refill, request a refill from your doctor, and shipping time.
- ☐ Refills can be requested via a call, web, our IVR, or our patient portal (explain the difference).
- ☐ We will send you text and email refill reminders if you provide your cell phone number and email address.
- ☐ When you get a new prescription from your prescriber, and it is the same dose, dosage form, directions for use, quantity, and within 2 weeks of your next fill date, we will automatically fill and ship it to you if you leave your credit card on file. If there are any changes to your prescription, we will call you for confirmation. Refills must still be requested.
- ☐ Are you interested in getting access to our patient portal? On our patient portal you can set up automatic refills, submit refill requests, print receipts, and view your medication history. Do you want to talk to our patient portal coordinator now? You can also email the team at patientportal@belmarpharma.com or transfer call to portal team at ext. 722.
- ☐ Would you like to consult with a pharmacist about your prescription?
- ☐ Is there anything else you can do for him/her?
- ☐ If you have any questions, please give us a call back. Enjoy the rest of your day!

8.0 FORM BACKUP USAGE

If the Pestle system is not available, obtain a paper hardcopy of Pestle Tasks from site "Library of Backup forms", maintained by site Quality units.

9.0 REFERENCES

- SOP 1.00.10 General LifeFile
- WI 1.00.10-15 Work Instruction for LifeFile – Memos, Note and Activities
- WI 1.00.10-07 Work Instruction for LifeFile – Managing the CS Bucket
- Pestle Task – Read and Understand

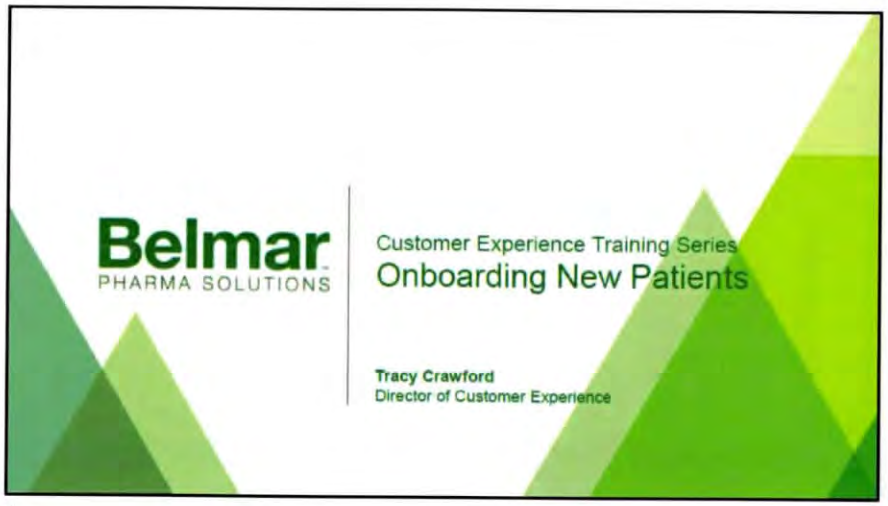
10.0 ATTACHMENTS

Not applicable

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Control Number / Justification
1.0	02/17/2023	New work instruction for LifeFile.	CCCN23-003

Attachment 4



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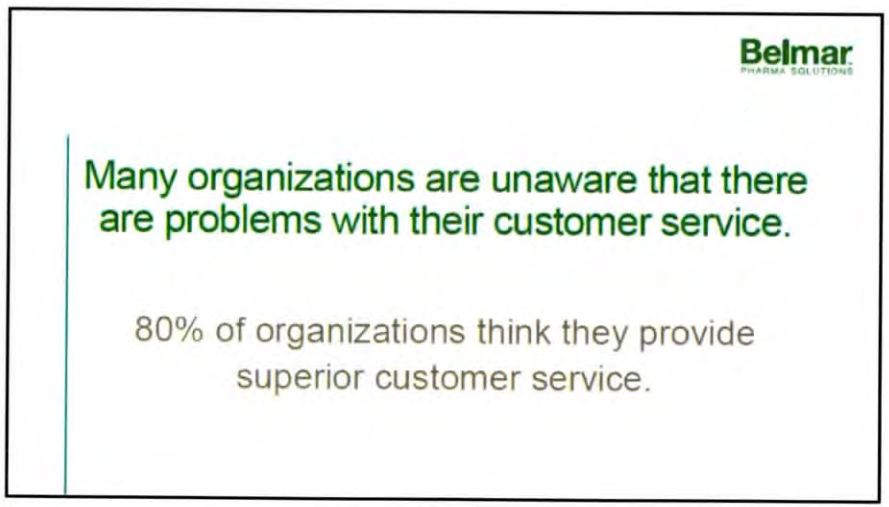

2

Belmar
PHARMA SOLUTIONS

…Only 8% of their customers felt the same way.

The Growing Power Of Consumers - Deloitte

3

DID YOU KNOW?

Belmar
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We are not the only game in town. There are competitors all over the country that want to win over our patients.

4

DO YOU REALIZE HOW IMPORTANT YOU ARE?

Belmar

73% of customers fall in love with a brand and remain loyal because of friendly customer service representatives.

Customer Service Impact Report – RightNow Technologies

5

DID YOU KNOW

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Face-to-Face Communication

- 55% Body Language
- 38% Tone of Voice
- 7% Words Used

6

DID YOU KNOW

Belmar

Telephone Communication

- 18% Words Used
- 82% Tone of Voice

7

VOCAL QUALITIES

Belmar

- Tone
  - Expresses feeling or emotion
- Inflection
  - Emphasizing words and syllables to enhance message
- Pitch
  - How high or deep voice sounds
- Rate
  - How many words spoken per minute
- Volume
  - How loud or soft a voice sounds

8

FRIENDLY SERVICE REMINDERS:

Belmar

- Tone is everything.
- Listen and don't talk over the patient or provider
- Don't get defensive. It's not personal.
- Never blame the doctor's office
- Keep it simple. Neither the clinic nor the patient will understand our pharmacy jargon (PV1, Assembly, etc.)
- If you make a mistake, we have your back. If another pharmacist or technician makes a mistake, have their back and thank the patient/clinic for the opportunity to fix it.
- Put labels on prescriptions straight. The same with the UPS labels on our shipments. We work too hard throughout the entire prescription process to have a sloppy presentation and the patient think we are second class.
- If we set expectations with our new doctors and patients, could some of our problems go away?

9

THE IMPORTANCE OF GETTING EMAIL ADDRESSES

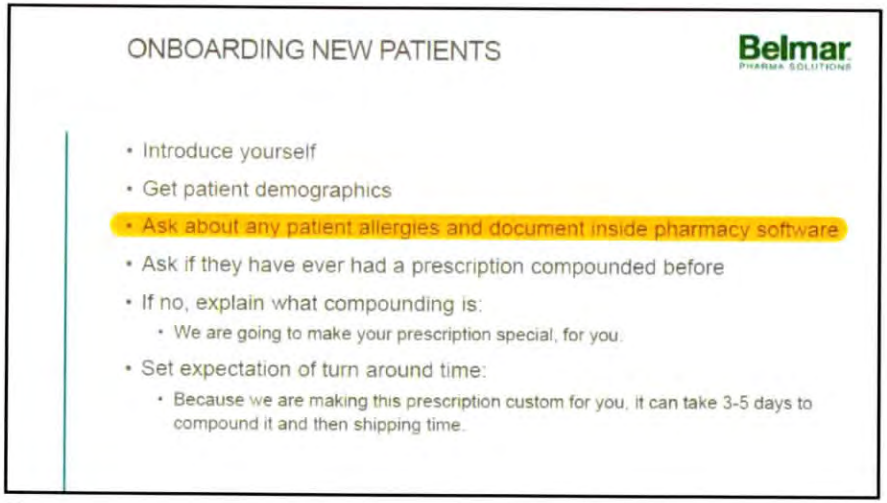
Belmar

- Patients
  - Order status updates
  - Billing
  - Tracking info
  - Refill reminders
  - Recalls
  - Do they want to be added to our patient eNewsletter? This is not mandatory.
- Doctors
  - Recalls
  - Prescription clarifications
  - Regulatory updates
  - Medication availability updates
  - Learning about additional services/medications

10

ONBOARDING NEW PATIENTS
Managing Expectations
Belmar

11


ONBOARDING NEW PATIENTS
Belmar
PHARMA SOLUTIONS
• Introduce yourself
• Get patient demographics
• Ask about any patient allergies and document inside pharmacy software
• Ask if they have ever had a prescription compounded before
• If no, explain what compounding is:
• We are going to make your prescription special, for you.
• Set expectation of turn around time:
• Because we are making this prescription custom for you, it can take 3-5 days to compound it and then shipping time.

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ONBOARDING NEW PATIENTS

Belmar PHARMA SOLUTIONS

- Get billing and shipping information and his/her email address. Let the patient know they should receive text messages and emails throughout the process.
- Talk about shipping options.
  - 95% of prescriptions leave the pharmacy within 5 days, how fast would you like to get your prescription after that?
  - Some medications may have special shipping rules, like they have to go overnight on ice.
  - If someone selects overnight, re-emphasize that we still need the time to make the prescription so it won't go out today. Shipping is shipping. Overnight does not expedite the compounding time.
- The patient can check the status of the prescription on the IVR by typing it into the automated phone system.

13

ONBOARDING NEW PATIENTS

Belmar PHARMA SOLUTIONS

- Let them know how they can submit a refill request:
  - On the pharmacy website
  - Give us a call:
    - Use the phone IVR system
    - Leave us a voicemail
    - Speak to a technician
  - Respond to a text message (if there are refills on file)
  - Some pharmacies in BPS have an app they can use to request a refill
- We would really appreciate two weeks to get your prescription to you.
- Since you are getting a 30/60/90-day supply, you will want to send in your refill on _____ day. I recommend setting a reminder on your calendar or in your phone.

14

ONBOARDING NEW PATIENTS

Belmar

- Would you like to consult with a pharmacist about your prescription?
  - If yes: park the call, and in your pharmacist ZAC group, let the pharmacists know there is a patient holding who would like to talk about their prescription. Give patient name and medication or doc ID number.
  - If no
- Thank them for letting us take care of their compounding needs. Say your name again and remind them to call us if they need us. We are happy to help!

15

NEW PATIENT CHECK LIST

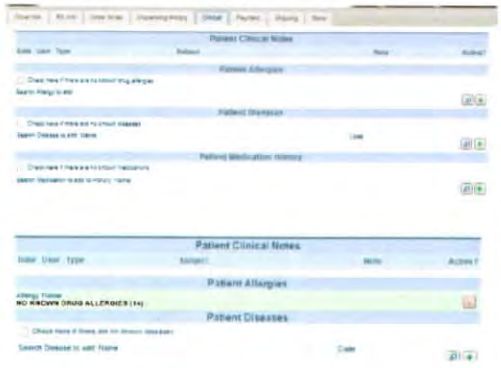
Belmar

- ✓ Introduce yourself
- ✓ Patient name
- ✓ DOB
- ✓ Address
- ✓ Cell phone
- ✓ Email for prescription updates
- ✓ Any known drug/food allergies, diseases, or medical conditions they would like us to make note of in the clinical tab.

16

WHERE TO DOCUMENT ALLERGIES IN LIFEFILE

Belmar

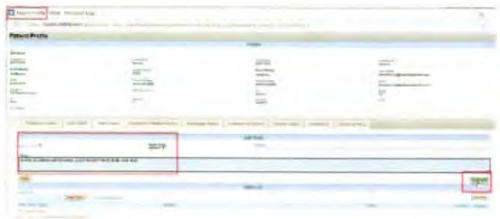


17

DOCUMENTING SEVERE ALLERGIES

Belmar

- A patient priority note should also be made for any severe allergies.
- If there is anything severe, the call should be passed to a pharmacist and the pharmacist should document reactions.



18

NEW PATIENT CHECK LIST

Belmar

- ✓Has the patient ever had a prescription compounded before?
- ✓Go over the prescription that was sent in
- ✓Cost as rx is written
- ✓How much would the patient like to fill? (1mo, 2mo, 3mo)
  - BUD dependent
  - Controlled substance rxes can be filled for amount written or less
- ✓Shipping options and compounding time

19

NEW PATIENT CHECK LIST

Belmar

- ✓Would the patient like to consult with a pharmacist?
- ✓Call us two weeks before your prescription runs out so we have time to compound your refill.
- ✓Is there anything else you can do for him/her?
- ✓My name is _____. it is really great to meet you. If there is ever anything I can do for you, please give me a call back.

20

THE GOALS OF PATIENT ONBOARDING

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- Gives us a chance to explain how what we do is special and specifically for him/her.
- Set realistic expectations with the patient.

21

Belmar PHARMA SOLUTIONS

THANK YOU!

22

Attachment 5

Formula Worksheet (standard)
11/3/2023 12:35:10 PM
Page 1

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

BATCH ESTRADIOL 20 MG/GM CREAM

NIOSH Hazard ☑

Flavor:

PCCA ID: TOPICAL Schedule: L 26801 Active ☑

Quantity made: 2800 GM **Class:** HORMONES Formula ID: 26801
Date made: ____/____/____
Lot number: _____ **Dispensing pack size:**
Beyond use date: ____/____/____ **Time:** ____:____ **Days to exp.** 120 **NDC1:** 26801
Pharmacist: _____ **Initials:** _____
Technician: _____ **Initials:** _____
Description: HAZARDOUS/ROOM TEMPERATURE
Equipment: TECH BLEND_____ RPH BLEND_____

Packaging: OPAQUE CONTAINER
Labeling: WEIGH/MIX:_____ FINISH:_____ YIELD:_____ LOT VERIFICATION RPH CK:_____
Hazard codess:

Ingredients & Notes	NIOSH Hazard	Schedule	Quantity used	QS	(Actual)	Opt.
1 ESTRADIOL MICRONIZED USP POWDER 0	☒	L	56 GM	☐	_____	☐
Mfg:_____ Lot #:_____ Exp. date:_____ Whlsr:_____						
Checked: ☐ Name or Initials: _____ (Each GM contains 0.02 GM or 2%) Ing. note:						
2 CREAM BASE 0	☐	L	2744 GM	☐	_____	☐
Mfg:_____ Lot #:_____ Exp. date:_____ Whlsr:_____						
Checked: ☐ Name or Initials: _____ (Each GM contains 0.98 GM or 98%) Ing. note:						

(Added all GM & GMS: 2,800.00)

Unit AWP: Time to make:

Mixing directions

Verify the information is correct when creating the log.
The pharmacist must be the pharmacist overseeing compounding (lot verification) the day the log is created and made.
The technician scanning and weighing the ingredients must be the technician named in the field.

Batch yield: This is the amount that this log will yield.
Qty remaining: This is the amount that this log will yield.

Weigh all the ingredients in the following order in accordance with directions below. All powders must be weighed in a powder containment hood and must be wet down prior to removing from hood.

Click the barcode icon for the first ingredient and scan the barcode containing the chemical ID located on the ingredient.
Place weigh paper on the scale and tare. Click the Record Balance Tare to record the zero weight.
Following the order of the listed ingredients, weigh the ingredient on the balance (within 3% range) and click "Get value from balance". Click OK. Weigh the base into an appropriately sized maz container.
Follow these instructions to scan and weigh all remaining ingredients.

1. Remove a small amount of base from weighed container and place into the unguator jar.
2. In the powder containment hood, place each powder into the unguator jar in the order that each active powder ingredient was weighed.
3. Remove another small amount of base from weighed container and add to the unguator jar. Place unguator blade and lid on jar and close, turn blade around and up and down, hand mixing prior to placing on unguator machine.
4. Assemble unguator jar and select the Less than 2% preprogrammed cycle. Once complete, remove mix from unguator jar and place into the maz container containing the remaining base.
5. Select an appropriate counter weight for the total weight of this log. Select Channel 12, a preprogrammed cycle and run. Once complete, perform a blend check on a glass slab. If needed, run channel 12 cycle again. Visually confirm there are no particles and mixture is uniform and smooth. Request a pharmacist blend check and initial.

On tab 3, scan the barcodes for all equipment/devices used and add to the log.

Finalize log and print log worksheet and Standard Batch Labels and chemical barcodes. Attach one standard batch label to log worksheet. Initial on weigh/mix line and finish line and document the yield. Attach the standard batch label and chemical barcodes to the mixing device and place in bucket for the lot verification pharmacist to check. The lot verification pharmacist will sign and date the Lot Verification RPH field confirming that all ingredients were scanned with appropriate beyond use dating, all calculations are correct, final product appearance is appropriate and correct quantity was made for the order.

Final product should be a smooth, white to off-white cream/gel

CALCULATIONS ARE BASED ON 2800 GMS (Strength x Quantity ÷ 1000)
Estradiol Powder 56 gm
Cream Base 2744 gm

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PK Software Inc

Formula Worksheet (standard)
11/3/2023 12:35:10 PM
Page 2

Women's International Pharmacy - AZ
12012 N. 111th Ave.
Youngtown, AZ 85363 Ph.

BATCH ESTRADIOL 20 MG/GM CREAM

NIOSH Hazard ☑

Flavor:

PCCA ID:

Schedule: L TOPICAL 26801 Active ☑

Note:

Date entered: 11/23/2005 12:51:30 PM Last modified: 11/3/2023 12:34:10 PM by: KARI ANNE

PK Software, Inc.

Attachment 6

Belmar PHARMA SOLUTIONS	Document Number: SOP 7.00.10	CHAPTER 7: Compounding Process - Sterile	Version: 1.0
	Document Title: Media Fill Trial for High-Risk Level CSPs		Document Status: Effective
			Effective Date: 02/17/2023
Author: Dana Larson	Authorized By: Anne Szilagyi		

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2.0 SCOPE 2
3.0 RESPONSIBILITY 2
4.0 DEFINITIONS 2
5.0 MATERIALS AND EQUIPMENT 2
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6.1 Background 2
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7.0 PROCESS MAP 3
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8.2 Media Fill Worksheet Requirements 5
8.3 Preparation for Media Fill 5
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8.5 Interpretation of Results 7
8.6 Failure of a Media Fill 7
8.7 Invalidation of a Media Fill 7
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Confidential

Belmar PHARMA SOLUTIONS	Document Number: SOP 7.00.10	CHAPTER 7: Compounding Process - Sterile	Version 1.0
	Document Title: Media Fill Trial for High-Risk Level CSPs		Document Status: Effective
			Effective Date: 02/17/2023
Author: Dana Larson		Authorized By: Anne Szilagyi	

1.0 PURPOSE

The purpose of this procedure is to describe how to validate the sterile filling process using microbiological growth medium in place of actual product during various processes of sterile compounding.

The purpose of a media fill trial is to assess the aseptic ability of the operator as well as to evaluate the processing steps and provide assurance of process control.

2.0 SCOPE

This procedure applies to all sterile compounding personnel and the Quality Unit.

3.0 RESPONSIBILITY

3.1 Sterile Compounding Personnel

3.1.1 It is the responsibility of sterile processing staff to follow this procedure.

3.2 Quality Unit and Management

3.2.1 It is the responsibility of Management to ensure that all sterile compounding personnel complete a media fill trial and that it encompasses the sterile processing procedures performed by that staff.

3.2.2 It is the responsibility of the Quality Unit to ensure this procedure is followed and audit for compliance.

3.2.3 It is the responsibility of the Pharmacist in Charge (PIC) to perform abbreviated media fills of at least 50 vials to demonstrate performance of aseptic manipulations. PIC will not prepare compounded sterile preparations in quantities greater than 50 vials for which they have successfully completed a media fill.

4.0 DEFINITIONS

Terms and definitions are available in Corporate Glossary.

5.0 MATERIALS AND EQUIPMENT

5.1 Cleaning supplies per SOP 3.00.01 and 3.00.02

5.2 Materials and equipment listed in Media Fill Worksheet

5.3 Incubator(s)

5.4 Tryptic Soy Agar (TSA) with neutralizer contact plates

6.0 GENERAL INFORMATION

6.1 Background

6.1.1 The skill of personnel to aseptically prepare sterile compounds is evaluated using this policy.

6.1.2 Media-fill challenge tests that simulate high-risk level compounding are also used to verify the mostchallenging process to compound a sterile preparation.

6.2 Required Training

6.2.1 Competencies and Written Exam

6.2.1.1 Personnel will successfully complete a written exam annually or with each media fill.

6.2.1.2 The competencies and risk of exposure to hazardous chemicals will be documented withevery media fill.

6.3 Frequency

6.3.1 Initially and before compounding sterile preparations for patients

6.3.2 Quarterly as defined in this procedure

6.3.3 As needed for requalification or corrective action, as defined in this procedure

7.0 PROCESS MAP

8.0 PROCEDURE

8.1 Media Fill Requirements

8.1.1 Media fills are to be completed after sterile compounding personnel pass a gowning qualification and complete and pass the sterile compounding training program. See 2.00.01 Sterile Compounding Personnel Qualifications, 7.00.01 Hand Hygiene and Garbing Hazardous, 7.00.02 Hand Hygiene and Garbing Nonhazardous.

8.1.2 Media fills will be completed by each sterile compounding technician and pharmacist for the sterile compounding process that they will perform.

8.1.3 Tryptic Soy Broth (TSB) media is used for this test. This media has been demonstrated to support the growth of a variety of microorganisms.

8.1.4 Vials for growth promotion will be drawn from each batch.

8.1.5 Media fills must be completed using the same equipment and in the same area where production occurs.

8.1.5.1 The media fills worksheet must document Primary Engineering Control (PEC) utilized.

8.1.6 Qualification will require passing 1 media fill for each media fill process being tested (i.e., 1 media fill trial for product produced in a vertical flow hood and 1 media fill trial for product produced in a horizontal flow hood).

8.1.7 Each media fill will simulate worst case conditions, in the event that compounding will occur all day, media fills must capture that.

8.1.8 Requalification will occur on any sterile personnel that have not compounded sterile products in more than 3 months or if requested by the Quality Unit.

8.1.9 Media fills must be conducted quarterly (every 3 months) on all active sterile compounders and pharmacists.

8.1.9.1 If the media fill is not completed every 3 months, the employee may not engage in

the production of sterile products until this requirement has been satisfied.

8.1.10 Media fills must be conducted whenever there is a significant change to the aseptic process.

8.1.11 Each media fill will include both inherent and corrective planned interventions as dictated by the media fill worksheet.

8.1.11.1 Inherent planned interventions are those which are inherent to the process and the verification of which are not recorded on a typical production batch but are to be recorded on the media fill worksheets. These may include but are not limited to aseptic material transfer, pump calibration, equipment assembly, hood setup, etc.

8.1.11.2 Corrective planned interventions are those which have historically been experienced but are not typically associated with the filing of an out of specification and subsequent investigation. Examples of positive corrective interventions include glove tears, breakage of vials, spill cleanup, etc.

8.1.11.3 Unplanned interventions are those which are not expected but did occur while in the process of completing the media fill. These must be documented on the media fill worksheet and investigated per procedure if required.

8.1.12 Media fills must be conducted under dynamic conditions typically encountered by the operator.

8.1.12.1 The number of personnel present must, at minimum, be reflective of maximum operating conditions (i.e., dayshift normal production) at all times during the media fill. In addition, the ISO 7 buffer room must contain the maximum allowable number of personnel (based on room certification) for a minimum of one hour. The personnel present may be made up of other compounding personnel, quality personnel, pharmacists, or other appropriately trained personnel.

8.1.12.2 There will be simulation of routine procedures such as garbing, hand hygiene, aseptic technique, product manipulations, etc.

8.1.12.3 The duration of the media fill will be at least equivalent to the largest batch size produced.

8.1.12.4 Maximum operator fatigue will be represented, and all unscheduled breaks documented in the applicable area of the worksheet.

8.1.13 Clear vials will be used, if available, for the sizes of vials required in the testing.

8.1.13.1 If clear containers are unavailable, extra care must be taken to ensure that no contamination is missed. If any uncertainty, the media will be drawn out into a syringe and reviewed for contamination. The reason for removal will be documented on the Media Fill Worksheet.

8.1.13.2 Vials will be inspected by appropriately trained personnel and in accordance with SOP *Visual Inspection of Sterile Solutions*.

8.1.13.3 All integral vials must be incubated. Non-integral vials may be rejected by the operator of quality personnel, but the number of vials rejected and the reason for rejection must be documented on the media fill worksheet. Cosmetic defects and other items not impacting container closure integrity may not be rejected and will be incubated.

8.1.14 Fill volume must be adequate to show growth, capable of contacting all interior surfaces of the vial and closure when swirled or inverted and allow adequate headspace to support the

growth of aerobic microorganisms. For example, media fill vials may be filled to the stated volume capacity of the vial without overfill.

8.1.15 Routine environmental monitoring must be conducted per SOP *Environmental Monitoring and Sampling*. At minimum, this includes PEC surface sampling at the completion of the media fill.

8.2 Media Fill Worksheet Requirements

8.2.1 Documentation of media fills will include, but not be limited to:

8.2.1.1 Specific PK Software log worksheet for the media fill completed

8.2.1.2 Date and workspace location of media fill

8.2.1.3 Start and stop time of media fill

8.2.1.4 Container/closure descriptions (type, lot number and size)

8.2.1.5 Volume filled

8.2.1.6 Filter brand/description and lot numbers/expirations date (if applicable)

8.2.1.7 Type of media used, lot number/expiration date and growth promotion date/results (if purchased, a certificate of growth promotion should be maintained on file)

8.2.1.8 Number of units filled

8.2.1.9 Number of units rejected at inspection and reason for rejection

8.2.1.10 Number of units incubated and incubation time/temperature

8.2.1.11 Number of positive units at the conclusion of the incubation

8.2.1.12 Final Results

8.3 Preparation for Media Fill

8.3.1 The sterile laboratory will be cleaned per SOP 3.00.01, "Cleaning and Maintenance of the Cleanroom Facility and SOP 3.00.02, "Deactivation, Decontamination, Disinfect and Cleaning of the Hazardous Sterile Areas."

8.3.2 Using PK software, prepare a log for the amount needed for the personnel performing the challenge (include overfill to ensure entire quantity of units can be prepared at one time). All media fills shall be conducted using the current compounding procedures and equipment.

8.3.3 Personnel performing the media fill will compile equipment and materials needed for the media fill; quantities are dependent on size of fill and the process being evaluated. Quantities and components are listed and verified on the media fill worksheet and will include the same items utilized in the normal production process being simulated whenever possible.

8.3.4 Document equipment and materials to be used on the media fill worksheet.

8.3.4.1 Equipment includes calibration dates and calibration due dates. All equipment must be within calibration to be utilized.

8.3.4.2 For non-ingredient materials sterilized or depyrogenated on site, include the autoclave/depyrogenation oven cycle and beyond use date.

8.3.4.3 For ingredient materials and items sterilize off-site, include the manufacturer, lot number, and beyond use date.

8.3.5 Prepare a 3% solution per media fill worksheet instructions.

8.3.5.1 Prior to entering the buffer room and filtering the solution, remove one aliquot of media

and place into a sterile vial.THIS IS THE POSITIVE CONTROL.

8.3.6 Once inside the buffer room, stage the direct compounding area (DCA) with all required equipment and materials following appropriate aseptic material transfer.

8.3.7 Begin the filling portion of the media fill trial, following aseptic technique as described in all applicable SOPs

8.3.7.1 Oil Solution Injectable: filter solution using the approved sterilizing filter into a sterile receiver.

8.3.7.2 Aqueous solutions: using repeater pump, attach sterilizing grade filter to tubing and filter directly into empty sterile vials.

8.3.8 Using a repeater pump, aseptically transfer the required amount of filtered media solutioninto sterile vials for the total amount needed to validate the personnel completing the challenge. Volume transferred depends on the process being simulated and may be between 5ml-10ml.

8.3.9 Aseptically insert sterilized rubber septum into the vial top using sterilized tweezers. Applyflip caps. A different color should be assigned to each person, if possible.

8.3.10 Remove all supplies from the PEC and clean according to SOP 3.00.01 and 3.00.02 depending on the area (hazardous or nonhazardous).

8.4 Post Media Fill

8.4.1 Fingertip and body sampling must be completed per SOP 11.00.17 Personnel Monitoring at the end of each media fill trial.

8.4.2 The Quality Unit will take possession of the filters, plates, and any other material required for analytical testing.

8.4.3 The Quality Unit will take possession of the finished media fill vials and incubate the samples and controls as follows:

8.4.3.1 Incubate at 20-25°C for the first 7 days.

8.4.3.2 The Quality Unit will visually examine each vial for growth

8.4.3.3 If no growth is present, incubate the vials at 30-35°C for an additional 7 days.

8.4.3.4 Quality personnel will visually examine each vial for growth.

8.4.3.5 Incubation time will total 14 days.

8.4.3.6 Any media filled units not incubated or found to be damaged during visual inspection must be accounted for and documented.

8.4.3.6.1 Immediately notify the Quality Manager to any damaged or questionable vials.

8.4.3.6.2 Cause for rejection must be documented.

8.4.3.6.3 Units found to have defects not related to integrity (e.g., cosmetic defect) should be incubated; units that lack integrity should be rejected.

8.4.3.6.4 If a vial is damaged and is not a representative sample of acceptable quality standards (e.g., container closure integrity has been compromised) it may be removed from the lot provided an investigation is conducted and photographic evidence is attached to the investigation to support removal.

8.4.3.6.5 If a vial is damaged and it is determined the vial may be a representative

sample of damage that may occur upon release to the market, it must remain with the lot to complete incubation.

8.4.4 After incubation, the testing vials should be clear and free from evidence of turbidity or growth.

8.4.4.1 Documentation of successful growth promotion is required for a passing result to ensure the media is capable of supporting growth after processing and filling.

8.5 Interpretation of Results

8.5.1 Sterile compounding may take place during the incubation period for the Media Fill Trial with full understanding that product will be discarded if the compounder fails the trial.

8.5.2 If no growth is noted after day 14, the media fill will be given a "conform" or "pass" to indicate a successful media fill.

8.5.3 Any units showing suspected growth will be brought to the attention of the Quality Manager and Sterile Compounding manager and investigated.

8.5.4 Growth in any vial will constitute a media fill failure.

8.5.5 The media fill results form must be closed out and signed off by the Quality Unit once results are finalized.

8.5.6 All results should be maintained in the employee file.

8.6 Failure of a Media Fill

8.6.1 If an operator has failed the media fill it must be repeated in its entirety.

8.6.2 Media fill failures must be investigated by the quality unit and may result in operator retraining or disqualification at the discretion of the quality unit and the PIC.

8.6.3 Organisms must be identified to the species level.

8.7 Invalidation of a Media Fill

8.7.1 Media fill invalidations should be rare and only under circumstances that would require a lot of finished product not to be released.

8.7.1.1 An example of an invalidated media fill would be if the operator had to evacuate the building due to fire or other safety hazard.

9.0 FORM BACKUP USAGE

If the Pestle system is not available, obtain a paper hardcopy of Pestle Tasks from site "Library of Backup forms", maintained by site Quality units.

10.0 REFERENCES

- SOP 2.00.01 – Sterile Compounding Personnel Qualification
- SOP 3.00.01 – Cleaning of the Sterile Areas
- SOP 3.00.02 – Deactivation, Decontamination, Disinfection and Cleaning of the Hazardous Sterile Areas
- SOP 11.00.15 – Out of Specification Results
- SOP 11.00.05 - Visual Inspection of Sterile Solutions
- SOP 11.00.19 - Environmental Monitoring - Sampling
- SOP 11.00.17 - Personnel Monitoring
- SOP 7.00.01 - Hand Hygiene and Garbing Hazardous

- SOP 7.00.02 - Hand Hygiene and Garbing Nonhazardous
- FORM 7.00.10-01 - Media Fill Results

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Control Number / Justification
1.0	02/17/2023	New SOP for Belmar Corporate. CCCN23-004 is for the introduction of this document into WIP-AZ master SOP index.	CCCN23-004

Attachment 7

Belmar PHARMA SOLUTIONS	Document Number: SOP 7.00.01	CHAPTER 7: Compounding Process – Sterile (503A)	Version: 1.0
	Document Title: Hand Hygiene and Garbing Hazardous Sterile Areas (503A – WIP-AZ)		Document Status: Effective
			Effective Date: 12/09/2022
Author: Arielle Bailey		Authorized By: Anne Szilagyi	

1.0 PURPOSE

The purpose of this procedure is to establish proper handwashing and garbing techniques for entry into the hazardous sterile areas.

2.0 SCOPE

This procedure applies to all sterile compounding staff, pharmacists, quality department, and any other person entering the hazardous areas. Hand hygiene and garbing processes are required in all compounding laboratories and are required for ensuring a safe quality drug is compounded.

3.0 RESPONSIBILITY

3.1 Sterile Compounding Staff

3.1.1 It is the responsibility of each employee authorized to enter the cleanroom to follow this procedure.

3.1.2 It is the responsibility of the sterile compounding staff to ensure anyone entering the cleanroom follows this procedure.

3.2 Quality Unit

3.2.1 It is the responsibility of the Quality Unit to understand and periodically review this process for compliance.

3.2.2 The Quality unit will be responsible for maintaining the requirements within this document.

4.0 DEFINITIONS

Terms and definitions are available in Corporate Glossary.

5.0 MATERIALS AND EQUIPMENT

5.1 Lab dedicated scrubs
5.2 Lab dedicated shoes
5.3 Lab coat (if applicable)
5.4 Hair net
5.5 Beard cover (if applicable)
5.6 Shoe covers
5.7 Hot and cold running water
5.8 Sink
5.9 Soap
5.10 Nail cleaning picks
5.11 Low lint wipes
5.12 ASTM gloves (Sterile and non-sterile)
5.13 N-95
5.14 Sterile suit
5.15 Sterile chemo gown
5.16 Sterile sleeves

6.0 MATERIALS AND EQUIPMENT

6.1 Pestle – electronic system used to document training tasks

7.0 GENERAL INFORMATION

7.1 General Rules

7.1.1 No food, drink, or gum are allowed in sterile lab or surrounding area(s).

7.1.2 Individuals experiencing rashes, sunburns, weeping sores, conjunctivitis, or acute respiratory infections must be excluded from working in the ISO classified areas compounding areas until condition is remedied to prevent an increased risk of microbial contamination of compounded sterile products.

7.1.3 Personnel must remove all visible jewelry, makeup/cosmetics, adornments, ear buds, outerwear, and any nonessential items to compounding prior to entering the clean room facility. No artificial nails or nail polish can be worn.

7.1.4 Sterile disposable garb must not be reused.

7.1.5 Sterile laundered garb must not be reused without being laundered and re-sterilized with a validated cycle.

7.1.6 If at any time items are picked up from the floor, gloves must be changed immediately.

7.1.7 If glove tears occur while garbing, immediately stop the garbing process and remove and discard garb, and re-glove.

7.1.8 If double gloved and second (or top glove) tears, remove the second set of gloves and discard and re-glove.

7.1.9 In the event of a double glove tear in the prep or buffer room, immediately leave the room and proceed to the anteroom to start the doffing process. See section 9.2. After all garb has been removed, rewash your hands and start the garbing process over.

7.2 Required Training

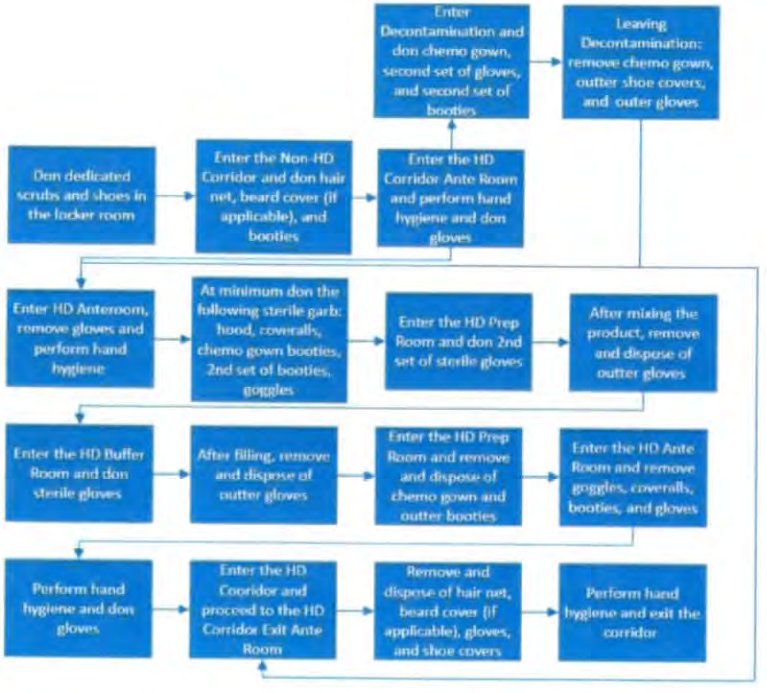
7.2.1 All sterile compounding personnel entering hazardous (HD) areas will be assessed for hand hygiene and garbing initially and quarterly thereafter. See SOP Sterile Compounding Personnel Qualification.

7.3 Frequency

7.3.1 Sterile hazardous gowns must be changed every 2-3 hours or immediately after a spill or splash.

7.3.2 Chemotherapy gloves must be changed every 30 minutess unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated. Documentation of this requirement will be found in each batch record.

8.0 PROCESS MAP



9.0 PROCEDURE

9.1 All lab personnel entering ISO 7 areas, HD drug storage, and the decontamination room must wear clean dedicated lab scrubs.

9.2 Lab dedicated scrubs and shoes will be housed in an employee locker onsite, a third party will pickup dedicated scrubs for washing weekly.

9.3 Street clothes (i.e., jeans) are not to be worn under scrubs, but dedicated undershirts are permitted.

9.3.1 If undergarments such as camisoles are worn in to work underneath another article of clothing, an employee may keep them underneath their scrubs during compounding.

9.4 Lab dedicated scrubs and shoes may only be worn in CNC and ISO classified areas.

9.5 Lab dedicated scrubs and shoes may not be worn in the shipping/receiving area, breakroom, outdoors or in the bathroom.

9.6 Entering Clean Corridor

9.6.1 The clean corridor is split between a dirty and clean side. Personnel that are not in dedicated scrubs must remain on the dirty side.

9.6.2 While on the dirty side, in addition to lab dedicated scrubs and shoes, personnel must also don a hair net. Use the mirror to ensure that all hair is secure in the hair net.

9.6.3 Don beard cover if applicable.

9.6.4 Wipe eyeglasses lens and frames with pre-wetted lens cleaning tissue, if applicable.

9.6.5 Using the bootie butler, don one bootie and place that foot over the line of demarcation to the clean side. Don the second bootie and place that foot onto the clean side as well, being sure to not let either boot touch the dirty side of the line of demarcation.

9.6.6 Visitors or lab personnel that are not entering the lab area(s) may wear a lab coat in the clean corridors as a substitute for lab scrubs.

9.7 Entering HD Corridor Anteroom

9.7.1 When entering the HD corridor anteroom all personnel must wash their hands.

9.7.2 Wet hands with warm water, avoid excessively hot water as it increases skin shedding.

9.7.3 Apply enough soap to cover all hand surfaces.

9.7.4 Wash your hands and wrists thoroughly for at least 30 seconds.

9.7.5 Rinse hands with warm water.

9.7.6 Dry hands thoroughly with a low lint wipe.

9.7.7 Don nonsterile gloves.

9.8 Entering ISO 7 HD Anteroom

9.8.1 When entering the ISO 7 HD anteroom all personnel must wash their hands, forearms down to elbows thoroughly for at least 30 seconds.

9.8.2 Remove nail pick from container.

9.8.3 Expose the skin of the arms up to the elbows.

9.8.4 Using foot pedals on the bottom of the sink adjust the water temperature to a comfortable lukewarm to warm level, avoid excessively hot water as it increases skin shedding.

9.8.5 Under warm running water remove debris from under nails using a disposable nail cleaning pick. Start with the thumb and clean nails away from the body.

9.8.6 Dispose of the nail pick.

9.8.7 Wet arms one at a time, from fingertips to forearms.

9.8.8 Pump soap into the palm of your hands.

9.8.9 Lather the soap up by rubbing palms together.

9.8.10 Perform the following tasks

Note: the following order does not depict a sequential process, but all steps must be performed

9.8.11 Clean the back of your hands using your palm.

9.8.12 Clean in between each finger by interlacing fingers. Clean each finger with rotational rubbing of each finger.

9.8.13 Clean cuticles by rubbing the cuticles into the palm of the opposite hand.

9.8.14 Using a sweeping motion clean in between index finger and thumb.

9.8.15 Use a circular motion to clean from the wrist to the elbow. Avoid using scrubbing motions.

9.8.16 Once both arms have been thoroughly washed, the operator will place his or her arms under the running water to rinse one at a time. The hands must be held upward during rinsing to allow the water to run from the fingertips down to the elbows.

9.8.17 If soap remains, rewet fingertips and arms starting with fingertips.

9.8.18 Keeping your hands and arms over the sink use a low lint towel to dry, separate towels must be used per arm.

9.8.19 While drying the hands and forearms move in a downward motion with the towel, do not move upward.

9.8.20 Thoroughly apply alcohol-based hand sanitizer to hands only and rub dry.

9.9 Aseptic Donning Sterile Gloves.

9.9.1 Prior to donning sterile gloves, glove packages must be examined for defects and expiration dating.

9.9.2 Choose the correct size of sterile gloves.

9.9.3 Open the outer glove package and carefully set the inner wrapping packaging containing the gloves on a clean table.

9.9.4 Unfold the inner packaging to expose the set of sterile gloves.

9.9.5 Using your index finger and thumb, grasp the exposed folded cuff of one glove and slip your free hand into the glove, maintaining the folded cuff.

9.9.6 Touch only the part of the glove that will be next to your skin.

9.9.7 With your gloved hand, slip your fingers into the cuff of the second glove.

9.9.8 Keep the gloved thumb tucked in to keep from touching your bare palm or wrist.

9.9.9 Pull on the second glove, keeping your hands above the waist.

9.9.10 Reach under the cuffed part of the glove to pull up or adjust the gloves.

9.9.11 Keep your hands in front of you and above the waist.

9.9.12 Spray hands with sterile 70% isopropyl alcohol (IPA).

9.9.13 Gloves must be routinely inspected for holes, punctures, or tears.

9.9.14 If gloves are torn or punctured during compounding, remove, and discard the contaminated gloves and don a clean pair.

9.10 Garbing For Entry to Prep & Buffer Room

9.10.1 Garbing cannot be done at the same time as doffing (de-garbing).

9.10.2 The anteroom is split into a "dirty" and "clean" side, personnel must remain on the "dirty" side of the anteroom until sterile garb is donned.

9.10.3 Spray low lint wipe with sterile 70% IPA, wipe bench from clean to dirty side with overlapping strokes.

Note: If using wall to garb, wipe the designated area on wall from top to bottom with sterile 70% IPA.

9.10.4 Select appropriate size sterile garb, and check packaging expiration dates and ensure packaging has no tears. If vacuum seal is no longer intact discard the garb.

9.10.5 Wipe sterile garb packaging with sterile 70% IPA focusing on areas that will be touched when opening and place on clean garbing bench.

9.10.6 Discard sterile 70% IPA wipes as often as necessary and replace them with a new saturated sterile 70% IPA wipe as needed.

9.10.7 Spray gloves with sterile 70% IPA allow hands to dry and don face mask (if applicable).

9.10.8 Spray gloves with sterile 70% IPA allow hands to dry. Carefully remove hood from its packaging only touching the inside, gently unfold hood do not shake hood open. Open and don hood, if hood needs adjusting pull from the inside to avoid touching the outer hood with gloves.

9.10.9 Spray gloves with sterile 70% IPA allow hands to dry. Open suit, gently pull suit from packaging only touching the inside, make sure the outside of suit does not touch the ground, body, bench or any other object within the anteroom.

9.10.10 Gather the suit's arms and legs to assist in garbing touching only the inside of the suit. Standing or leaning against wall very carefully place one leg into the suit, repeat with the other leg. Bring suit up over shoulders and carefully insert one arm in at a time. Using the mirror, make sure the hood is fully tucked into the suit. Cross legs if necessary to zip suit. Fold flap over.

9.10.11 Spray gloves with sterile 70% IPA allow hands to dry. Remove one boot from packaging touching the inside of the boot. Sitting or standing put one boot on at a time rotating fully booted foot to the clean side of the anteroom. Repeat step for second boot.

9.10.12 Spray gloves with sterile 70% IPA allow hands to dry. Sitting or standing, don 2nd pair of sterile boot covers.

9.10.13 Spray gloves with sterile 70% IPA allow hands to dry. Don goggles by only touching the straps, adjust goggles to make sure no skin is showing.

9.10.14 Spray gloves with sterile 70% IPA allow hands to dry. Don sterile chemo gown, pull the gown up the arms and onto the shoulders, secure neck closure and tie in back.

9.10.15 Spray gloves with sterile 70% IPA allow hands to dry. Don sterile chemo sleeves. Touching only the inside of sleeves, slide sleeves up to the shoulder.

Note: Sterile chemo sleeves are only required by personnel compounding in the prep room.

9.10.16 Spray gloves with sterile 70% IPA. Check the mirror to make sure no skin is showing, and no holes or tears are in the suit. Do not enter the cleanroom with skin or scrubs exposed.

9.10.17 If suit has holes or tears while garbing cross back over to the dirty side. Remove garb and start garbing process over.

9.10.18 If suit tears occur while compounding in prep room or buffer room immediately exit to ISO 7 anteroom. See section 9.2

9.11 Entry to ISO 7 HD Prep Room

9.11.1 Upon entry to prep room spray gloves with sterile 70% IPA and allow hands to dry. Don second pair of sterile gloves. See section 8.8 aseptic donning of sterile gloves.

9.12 Moving from ISO 7 HD Prep Room to ISO 7 HD buffer Room

9.12.1 While in the powder BSC, remove sterile chemo sleeves and second pair of gloves. Discard in waste bag inside of hood before moving to buffer room.

9.12.2 If not wearing chemo sleeves, discard second pair of gloves in proper waste bag before moving to buffer room.

9.13 Entry to ISO 7 HD Buffer Room

9.13.1 Upon entry to buffer room spray gloves with sterile 70% IPA allow hands to dry. Don a second pair of sterile gloves. See section 8.8 aseptic donning of sterile gloves.

9.14 Entering Decontamination Room

9.14.1 While on the dirty side, don a nonsterile chemo gown and secure the gown by tying it in the back.

9.14.2 Don second pair of boot covers, one at a time, stepping double booted foot over line of demarcation. Repeat for second boot.

9.14.3 Don nonsterile gloves over chemo gown.

10.0 REMOVAL OF GARB

10.1 Exiting ISO 7 Buffer Room to ISO 7 Prep Room

10.1.1 Remove gloves in BSC

Pull first glove off, place glove in the palm of double gloved hand carefully slip finger underneath cuff of glove and remove glove. Discard gloves in waste trace HD bag inside of BSC.

Non compounding personnel may discard gloves into a trace HD waste bag.

10.1.2 Proceed to ISO 7 prep room.

10.2 Exiting ISO 7 Prep Room to Anteroom

10.2.1 Next to the line of demarcation but remaining on clean side of the prep room remove chemo gown. Slowly and deliberately pull the gown away from the body in an inside out fashion rolling the gown into a ball. Discard chemo gown into a trace HD waste bag.

10.2.2 Remove outer sterile boot one at a time stepping the single booted foot to the dirty side. Repeat step for second boot. Discard boots into a trace HD waste bag.

Note: Due to limited space, the single booted foot may touch the outer line of demarcation

10.2.3 Proceed to the dirty side of the Anteroom.

10.3 Exiting ISO 7 Ante Room to HD Corridor

10.3.1 On the dirty side of the anteroom remove sterile boot covers. Discard boots into a trace HD waste bag.

10.3.2 Remove goggles.

10.3.3 Unzip suit halfway and remove hood. Discard hood into a trace HD waste bag.

10.3.4 Finish unzipping suit, roll the collar back past the shoulders. Using gloved hands reach and pull sleeves down over the glove remove one hand from the suit then repeat on the other side. Roll the suit down to the floor. Remove one leg from the suit and repeat with the other leg. Discard suit into a trace waste bag.

10.3.5 Remove face mask (if applicable)

10.3.6 Remove second pair of gloves. Pull first glove off without touching the wrist or the skin, place glove in the palm of the gloved hand. Carefully slip finger underneath the cuff of the glove, remove glove. Place discarded gloves in trace waste bag.

10.3.7 Wash hands for 30 seconds. Dry hands with low lint wipes.

10.3.8 Don nonsterile gloves.

10.3.9 Exit ISO 7 anteroom.

10.4 Exiting Decontamination Room

10.4.1 Slowly and deliberately pull the gown away from the body in an inside out fashion rolling the gown and gloves into a ball. Discard chemo gown into a trace HD waste bag.

10.4.2 Remove boots and cross over line of demarcation.

10.5 Exiting HD Corridor Anteroom Exit

10.5.1 Remove hair net and place in trash.

10.5.2 Remove second pair of shoe covers.

10.5.3 Wash hands for 30 seconds. Dry hands with low lint wipes.

10.5.4 Leave hazardous corridor.

11.0 REFERENCES

- Competency – Pestle Task – Hand Washing and Garbing Related Practices for Hazardous Sterile Compounding – Initial Training
- Competency – Pestle Task – Hand Washing and Garbing Related Practices for Sterile Compounding – Quarterly Training (Done with Media Fills)

12.0 ATTACHMENTS

Not Applicable

13.0 HISTORY

Version Number	Date Effective	Description of Change	Change Control Number / Justification
1.0	12/09/2022	New corporate procedure for all 503A facilities. CCCN22-007 will represent the corporate approval and adoption of the procedure into WIP-AZ.	CCCN22-007

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Attachment 8

Belmar PHARMA SOLUTIONS	Document Number: 7.00.02	CHAPTER 7: Compounding Process – Sterile (503A)	Version: 1.0
	Document Title: Hand Hygiene and Garbing Nonhazardous Sterile Area (503A – Sterile – WIP-AZ)		Document Status: Effective
			Effective Date: 12/09/2022
Author: Arielle Bailey		Authorized By: Anne Szilagyi	

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1.0 PURPOSE

The purpose of this procedure is to establish proper handwashing and garbing techniques for entry into the non-hazardous sterile areas.

2.0 SCOPE

This procedure applies to all sterile compounding staff, pharmacists, quality department, and any other personnel entering the sterile lab areas. Hand hygiene and garbing processes are required in all sterile compounding cleanrooms.

3.0 RESPONSIBILITY

3.1 Sterile Compounding Staff

3.1.1 It is the responsibility of each employee authorized to enter the cleanroom to follow this procedure.

3.1.2 It is the responsibility of the sterile compounding staff to ensure anyone entering the cleanroom follows this procedure.

3.2 Quality Unit

3.2.1 It is the responsibility of the Quality Unit to understand and periodically review this process for compliance.

3.2.2 The quality unit will be responsible for maintaining the requirements within this document.

4.0 DEFINITIONS

Terms and definitions are available in Corporate Glossary.

5.0 MATERIALS AND EQUIPMENT

5.1 Lab dedicated scrubs
5.2 Lab dedicated shoes
5.3 Hair net
5.4 Beard cover (if applicable)
5.5 Shoe covers
5.6 Hot and cold running water
5.7 Sink
5.8 Soap
5.9 Nail cleaning picks
5.10 Low lint wipes
5.11 Gloves (sterile and non-sterile)
5.12 Sterile hood
5.13 Sterile coveralls
5.14 Sterile sleeves
5.15 Lab coats (sterile and non-sterile)
5.16 Pestle – electronic system used to document training tasks

6.0 GENERAL INFORMATION

6.1 No, food, drink, or gum are allowed in the sterile lab or surrounding area(s).

6.2 Individuals experiencing rashes, sunburns, weeping sores, fresh tattoos, conjunctivitis, or acute respiratory infections must be excluded from working in the ISO classified areas until condition is remedied to prevent an increased risk of microbial contamination of compound sterile products.

6.3 Personnel must remove all visible jewelry, makeup/cosmetics, adornments, ear buds, outerwear, and any nonessential items to compounding prior to entering the clean room facility. No artificial nails or nail polish can be worn.

6.4 Sterile disposable garb must not be reused.

6.5 Sterile laundered garb must not be reused without being laundered and re-sterilized with a validated cycle.

6.6 If at any time items are picked up from the floor gloves must be changed immediately.

6.7 If glove tears occur while garbing immediately stop the garbing process and remove and discard garb, and re-glove.

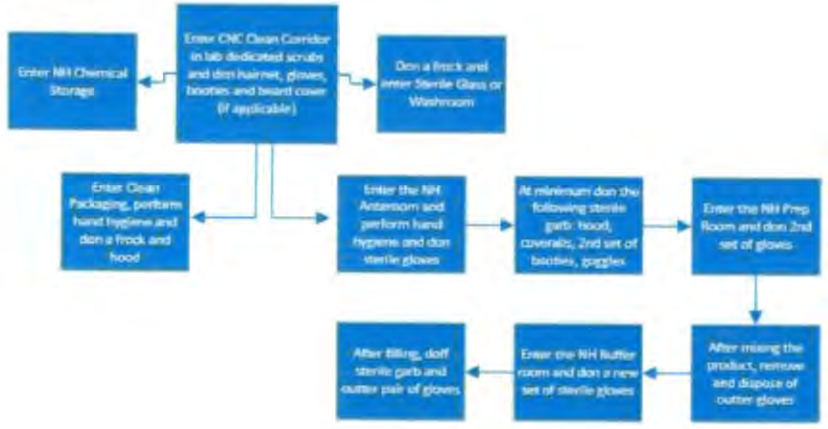
6.8 If double gloved and second (or top glove) tears remove second set of gloves discard and re-glove.

6.9 In the event of a double glove tear in the prep room or buffer room immediately leave room and proceed to anteroom to start the doffing process. See section 9.2. After all garb has been removed rewash hands and start garbing process over.

6.10 Required Training

6.10.1 All sterile compounding personnel entering the sterile cleanroom area(s) will be assessed for hand hygiene and garbing initially and quarterly thereafter. Training Tasks are documented within Pestle. See SOP Sterile Compounding Qualification

7.0 PROCES MAP



Confidential

8.0 PROCEDURE

8.1 Scrubs and Dedicated Shoes

8.1.1 All lab personnel entering the CNC and ISO classified areas must wear lab dedicated scrubs and shoes.

8.1.2 Lab dedicated scrubs will be housed in an employee locker onsite, a third party will pick up dedicated scrubs for washing weekly.

8.1.3 Street clothes (i.e., jeans) are not to be worn under scrubs, but dedicated undershirts kept onsite in an employee's locker are permitted

8.1.4 If undergarments such as camisoles are worn in to work underneath another article of clothing, an employee may keep them underneath their scrubs during compounding.

8.1.5 Lab dedicated scrubs and shoes may only be worn in CNC and ISO classified areas.

8.1.6 Lab dedicated scrubs and shoes may not be worn in the shipping/receiving area, breakroom, outdoors or in the bathroom.

8.2 Entry to Clean Corridor

8.2.1 The clean corridor is split between a dirty and clean side. Personnel not in dedicated scrubs must remain on the dirty side.

8.2.2 While on the dirty side in addition to lab dedicated scrubs and shoes, personnel must don a hair net, use the mirror to ensure all hair is secure in the hair net.

8.2.3 Don beard cover if applicable.

8.2.4 Wipe eyeglasses lens and frames with pre-wetted lens cleaning tissue (if applicable).

8.2.5 Don nonsterile gloves.

8.2.6 Using the bootie butler don one boot cover at a time stepping the booted foot over the line of demarcation. Repeat for other foot.

8.2.7 Visitors or lab personnel that are not entering classified area(s) may wear a lab coat in the clean corridor as substitute for lab scrubs. Don acceptable PPE at the entrance of the clean corridor.

8.3 Entering ISO 7 Non-Hazardous Anteroom

8.3.1 When entering the ISO 7 anteroom all personnel must wash their hands, forearms down to elbows thoroughly for at least 30 seconds.

8.3.2 Expose the skin of the arms up to the elbows.

8.3.3 Remove nail pick from container.

8.3.4 Using foot pedals on sink adjust water temperature to a comfortable lukewarm to warm level, avoid excessively hot water as it increases skin shedding.

8.3.5 Under warm running water remove debris from under nails using a disposable nail cleaning pick. Start with thumb, clean nails away from the body and into the sink.

8.3.6 Dispose of nail pick.

8.3.7 Soak arms from fingertips to forearms.

8.3.8 Pump soap into palm of hands.

8.3.9 Lather the soap up by rubbing palms together.

8.3.10 Perform the following tasks

8.3.11 Note: the following order does not depict a sequential process, but all steps must be performed.

8.3.12 Clean back of hands with palms.

8.3.13 Clean in between each finger by interlacing finger. Clean each finger with rotational rubbing of each finger.

8.3.14 Clean cuticles by rubbing the cuticles into palms of opposite hand.

8.3.15 Using a sweeping motion clean in between index finger and thumb.

8.3.16 Use a circular motion to clean the wrist to the elbow. Avoid using scrubbing motion.

8.3.17 Once both arms have been thoroughly washed, the operator will place his or her arms under the running water to rinse away the soap. Allow water to run from fingertips down to elbows.

8.3.18 If soap remains, rewet fingertips and arms starting with fingertips.

8.3.19 With hands and arms over the sink use a low lint towel to pat hands dry starting at the fingertip's dry arms in a unidirectional manner down to elbows never go back up. Use at least 1 dry wipe per arm. Separate towels used per arm.

8.3.20 Thoroughly apply alcohol-based hand sanitizer to hands only and rub dry.

8.4 Aseptic Donning Sterile Gloves.

8.4.1 Glove packages must be examined for defects and expiration date verification.

8.4.2 Choose the correct size of sterile gloves.

8.4.3 Open the outer glove package and carefully set the inner wrapping packaging containing the gloves on a clean table.

8.4.4 Unfold the inner packaging to expose the set of gloves.

8.4.5 Starting with one hand, use the index finger and thumb to grasp the exposed folded cuff of one glove and slip your free hand into the glove, maintaining the folded cuff.

8.4.6 Touch only the part of the glove that will be next to your skin.

8.4.7 With your gloved hand, slip your fingers into the cuff of the second glove.

8.4.8 Keep the gloved thumb tucked in to keep from touching your bare palm or wrist.

8.4.9 Pull on the second glove, keeping your hands above the waist.

8.4.10 Reach under the cuffed part of the glove to pull up or adjust the gloves.

8.4.11 Keep your hands in front of you and above the waist.

8.4.12 Spray hands with sterile 70% isopropyl alcohol (IPA).

8.4.13 Gloves must be routinely inspected for holes, punctures, or tears.

8.4.14 If gloves are torn or punctured during compounding, remove, and discard the contaminated gloves and don a clean pair of gloves.

Belmar PHARMA SOLUTIONS	Document Number: 7.00.02	CHAPTER 7: Compounding Process – Sterile (503A)	Version 1.0
	Document Title: Hand Hygiene and Garbing Nonhazardous Sterile Area (503A – Sterile – WIP-AZ)		Document Status: Effective
			Effective Date: 12/09/2022
Author: Arielle Bailey		Authorized By: Anne Szilagyi	

8.5 Garbing For Entry to Prep & Buffer Room

8.5.1 The Anteroom is split by a yellow line of demarcation to a "dirty" side and a "clean"side. personnel must remain on the "dirty" side of the anteroom until sterile garb is properly donned.

8.5.2 Spray a low lint wipe with sterile 70% IPA, wipe the bench from clean to dirty side with overlapping strokes.

8.5.3 Note: If using wall to garb, wipe designated area on wall from top to bottom with sterile 70% IPA.

8.5.4 Select appropriate size sterile garb, check packaging expiration dates, and ensure packaging has no tears. If the vacuum seal is no longer intact discard the garb.

8.5.5 Wipe sterile garb packaging with sterile 70% IPA focusing on areas that will be touched when opening and place on clean bench.

8.5.6 Discard sterile 70% IPA wipes as often as necessary and replace with a new saturated sterile 70% IPA wipe as needed.

8.5.7 Spray gloves with sterile 70% IPA allow hands to dry and don face mask (if applicable).

Note: Prudential hoods require the use of sterile surgical masks in addition to the built-in mask attached to the hood.

8.5.8 Spray gloves with sterile 70% IPA allow hands to dry. Carefully remove hood from its packaging only touching the inside. Gently unfold the hood, do not shake the hood open. Open and don hood, if hood needs adjusting pull from the inside to avoid touching the outer hood with gloves.

8.5.9 Spray gloves with sterile 70% IPA allow hands to dry. Open suit, gently pull suit from packaging only touching the inside, make sure the outside of suit does not touch the ground, body, bench or any other object within the anteroom.

8.5.10 Gather the suits arms and legs to assist in garbing touching only the inside of the suit. Standing or leaning against wall very carefully place one leg into the suit, repeat with the other leg. Bring suit up over shoulders and carefully insert one arm in at a time. Using the mirror make sure the hood is fully tucked into the suit. Cross legs if necessary to zip suit. Fold flap over the zipper.

8.5.11 Spray gloves with sterile 70% IPA allow hands to dry. Remove one boot from packaging touching the inside of the boot. Sitting or standing put one boot on at a time rotating fully booted foot to the clean side of the anteroom. Repeat step for second boot.

8.5.12 Spray gloves with sterile 70% IPA allow hands to dry. Don sterile sleeves. Touching only the inside of sleeves slide sleeves up to the shoulder.

Note: Sterile sleeves in addition to sterile garb are only required for personnel weighing and mixing in the prep room.

8.5.13 Spray gloves with sterile 70% IPA allow hands to dry. Don goggles by only touching the straps, adjust goggles to make sure no skin is showing.

8.5.14 Spray gloves with sterile 70% IPA. Check the mirror to make sure no skin is showing, and no holes or tears are in the suit. Do not enter the ISO 7 Prep Room with skin or scrubs exposed.

8.6 Entry to ISO 7 Prep Room

8.6.1 Upon entry to prep room spray gloves with sterile 70% IPA allow hands to dry. Don a second pair of sterile gloves. See section 8.6 aseptic donning of sterile gloves.

8.7 Moving From ISO 7 Prep Room to ISO 7 Buffer Room

8.8 Entry to ISO 7 Buffer Room

8.8.1 Before entering the buffer room discard sterile sleeves (if applicable) and a second pair of gloves.

8.8.2 Upon entry to the buffer room spray gloves with sterile 70% IPA allow hands to dry. Don second pair of sterile gloves. See section 8.6 aseptic donning of sterile gloves.

8.9 Entering Clean Packaging Room

8.9.1 When entering the ISO 7 clean packaging anteroom all personnel must wash their hands, forearms down to elbows thoroughly for at least 30 seconds. See section 8.5

8.9.2 Don sterile gloves. See section 8.6 aseptic donning of sterile gloves.

8.9.3 Spray low lint wipe with sterile 70% IPA, wipe table/cart with overlapping strokes.

8.9.4 Select the appropriate size of sterile garb, check packaging expiration dates and ensure packaging has no tears, if the vacuum seal is no longer intact discard the garb.

8.9.5 Wipe sterile garb packaging with sterile 70% IPA focusing on areas that will be touched when opening and place on clean table/cart.

8.9.6 Spray gloves with sterile 70% IPA allow hands to dry. Carefully remove hood from its packaging only touching the inside, gently unfold hood do not shake hood open. Open and don hood, if hood needs adjusting pull from the inside to avoid touching the outer hood with gloves.

8.9.7 Pull sterile lab coat from the packaging using the tag. Unzip lab coat, put one arm through at a time. Keeping both hands inside sleeves zip up lab coat. Finish pulling hands through sleeves.

8.9.8 Don sterile boots one at a time.

8.9.9 Upon entering the clean packaging room don second pair of sterile gloves. See section 8.6 aseptic donning of sterile gloves.

8.10 Entering the Wash Room

8.10.1 Prior to entering the washroom don a nonsterile lab coat in the clean corridor.

8.10.2 Don a 2nd pair on top of the lab coat.

8.11 Entering Sterile Glass

8.11.1 Prior to entering the sterile glass room don a nonsterile lab coat in the clean corridor.

8.11.2 Don a 2nd pair on top of the lab coat.

9.0 FORM BACKUP USAGE

If the Pestle system is not available, obtain a paper hardcopy of Pestle Tasks from site "Library of Backup forms", maintained by site Quality units.

10.0 REFERENCES

- Pestle Competency Task – Hand Washing and Garbing Related Practices for Non-Hazardous Sterile Compounding – Initial Training
- Pestle Competency Task – Hand Washing and Garbing Related Practices for Non-Hazardous Sterile Compounding – Quarterly Training (Done with Media Fills)

11.0 ATTACHMENTS

Not applicable

12.0 HISTORY

Version Number	Date Effective	Description of Change	Change Control Number / Justification
1.0	12/09/2022	New corporate procedure for all 503A facilities. CCCN22-008 will represent the corporate approval and adoption of the procedure into WIP-AZ.	CCCN22-008

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SUMMARY OF UNSATISFACTORY CONDITIONS

	DEFICIENCY	CHECK IF *
1)	PIC Mogen was verifying sterile compounding procedures and prescriptions but had not completed a media-fill in the last six month.	
2)	Hazardous waste is disposed of in regular trash.	
3)	Reviewed 6 patient profiles 4 had no allergies and 5 had no disease states/medical conditions, none of the 6 had prescriptions from other pharmacies or OTCs.	
4)		
5)		
6)		
7)		
8)		
9)		
10)		

IMMEDIATE CORRECTIVE ACTION IS REQUIRED (I.E., CONTINUING OPERATION WOULD CONSTITUTE A THREAT TO PUBLIC HEALTH AND WELFARE)

WOMEN'S INTERNATIONAL PHARMACY

Response to Summary of Unsatisfactory Conditions

1. Effective November 1, 2023, with the implementation of updated USP 797 for sterile compounding, designated personnel with direct oversight of compounding personnel will not verify sterile compounding procedures or prescriptions until they have completed garbing competency, media fill with post gloved fingertip testing and surface sampling with passing results at least every 12 months. If compounding, these competency assessments will be performed every 3 months.

2. While Women's International Pharmacy, Inc. ("WIP") compounds with hazardous *drugs* as defined by NIOSH/USP 800, we do not routinely compound/handle hazardous *waste* defined by EPA/RCRA. WIP follows federal, state and local laws for hazardous waste disposal including 40 CFR 261.7 Residues of Hazardous Waste in Empty Containers. If a container is not empty as defined by federal law, WIP utilizes 123 Logistics for disposal.

3. Women's International Pharmacy, Inc. ("WIP") staff collect allergy, condition and other medication information from patients at every point of contact. Staff have been trained to WI-1.00.10-20 Work Instruction for LifeFile – Contact the Patient and Customer Experience Training Series: Onboarding New Patients. All staff will complete retraining before November 15, 2023 to emphasize the importance of obtaining all information necessary for pharmacists to perform DUR. Additionally, WIP sends an email to each patient annually during their birthday month asking them to update their profile, including allergies, conditions and other medications so WIP has the most up-to-date information on file.

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist Application
Non-Refundable $250 fee

Rev (06/28/2022)

Section 1: Select how will you be obtaining your Nevada Pharmacist Registration

☒ **Examination**

☐ **Score Transfer** (Transfer your NAPLEX SCORE to Nevada within 89 days after taking your exam at https://nabp.pharmacy/ before completing this application.)

☐ **Reciprocation** (Complete NABP's Electronic Licensure Transfer Program (e-LTP) application at https://nabp.pharmacy/ before completing this application.)

Are you submitting this application to RETAKE the NAPLEX and/or MPJE? ☒ Yes ☐ No

Section 2: General Information

First: Rakan Middle: Munir Last: Sayegh

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted] Midvale Terrace

City: Henderson State: NV Zip: 89074

Telephone: [redacted] Email: [redacted]

Section 3: Employment Information

Pharmacy Name: _____ NV Pharmacy License # (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 4: College of Pharmacy Information

School Name: Roseman University

Address: 11 Sunset Way

City: Henderson State: NV Zip: 89014

Country/Territory/Province: USA

Graduation Date: 2022 Degree: ☒ PharmD ☐ BS in Pharmacy ☐ Other

Section 5: ONLY COMPLETE this section if you are applying for a Nevada Pharmacist Registration by RECIPROCATION.

Original State of licensure/registration you are reciprocating from must be active and issued by exam (passing the NAPLEX and that state's MPJE).

State: _____ License #: _____ Date of Issuance: _____ Expiry Date: _____

Section 6: List all pharmacist license/registration you have/had in other states. Use another sheet if additional space is needed.								
State	License/ Registration #	Issued Date	Expiry Date	License/Registration Status (check applicable box)				
				Active	Inactive	Expired	Revoked	Surrendered

Section 7: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 8: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 9: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		X
3. Have you been the subject of a board citation or administrative action whether completed or pending in <u>any</u> state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		X

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Rakan Sayegh

Print Name

Original Signature, no copies or stamps accepted

11/5/23

Date

Board Use Only	Date Received: 1/4/24	Amount: 250-CC
	NAPLEX:	MPJE:

11

11A

Back To Dashboard

Renewal Application
Pharmacist

Application Fee :	$200.00
Convenience Fee :	$10.00
License Number :	16142
License Type :	Pharmacist
New Expiration Date :	10/31/2025

Renewal Type

Please confirm the status that you are renewing before moving to the next section.

(•) Ac ive ( ) Inactive [Proceed to Renew]

Personal Information

First Name : HaiDuong

Middle (ini ial only) :

Last Name : Ngo

License # : 16142

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA :

Military Address : ☐

Street : [redacted]WATERBURY LN

Country : United States

City : HUNTINGTON BEACH State : California Zip : 92646

Practice Phone : (XXX) XXX-XXXX Practice Fax : (XXX) XXX-XXXX

☐ Select if the Practice Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Home Address :

Military Address : ☐

Street : [redacted]Waterbury Lane

Country : United States

City : Huntington Beach State : California Zip : 92646

Home Phone : (XXX) XXX-XXXX Cell Phone : [redacted]

Email Address : [redacted] Fax : (XXX) XXX-XXXX

☑ Select if he Home Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Sex : Female

Practice License Number: Specialty:

Nevada Business License Information - Check appropriate answer

- (●) **I DO NOT** have a Nevada Business license number.
- ( ) **I HAVE APPLIED** for a Nevada Business License with he Nevada Secretary of State in Compliance with provisions of NRS Chapter 76 and my applica ion is pending.
- ( ) I have a Nevada Business License number assigned by the Secretary of State in compliance with he provisions of NRS Chapter 76789066.

Name on Business License :

Business License # :

Child Support Information – Check appropriate answer

- (●) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to he order.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or o her public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in he Armed Forces of the United States and separated from such service under condi ion o her than dishonorable	( ) Yes (●) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions o her than dishonorable	( ) Yes (●) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the Na ional Oceanic and Atmospheric Administration of the United States in the capacity of he commissioned officer while on active duty in defense of the United States and separated from such service under conditions o her than dishonorable?	( ) Yes (●) No

Legal Information

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whe her completed or pending in any state? ○ Yes ◉ No

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ◉ Yes ○ No

The California State Board of Pharmacy has place my CA RPH license on probation for 5 years effective 4/21/2022. My CA RPH license i s placed on probation as a result of the Stipulated Settlement of CA Board Accusation case #7025. The AC #7025 case was primarily a case about failure to comply with the RPH Corresponding Responsibilities regarding controlled substances. I was part owner, and PIC of Top Drugs Pharmacy from 2018 to 2022 when I was audited by the CA Board of pharmacy inspector during a routine pharmacy inspection in 2020. The Board Inspector audited my controlled prescriptions, and discovered that I was not in compliance with the RPH Correspon ding Responsibilities and Red Flags in filling controlled prescriptions.

Document Name	Document Type	Date	Link	Action
AC 7025, HaiDuong Ngo	Legal - Question 4	10/28/2023	Document Details	

Document Name : Document Type : Legal - Ques ion 4

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload | Cancel

Board Administrative Action :

State : Select Date : 04/21/2022

Case # : AC 7025

Criminal Action :

State : Select Date : MM/DD/YYYY

Case # :

County : Court :

CE Hours

Active ☑ By checking his box you certify you have completed ALL required CE Hours due for the 2021/2023 Renewal period. (Dated from Nov. 1, 2021 – Oct. 31, 2023; 1.25hrs per mo). The exemp ion period is 2yrs after graduation only

Acknowledgement and Declaration

I understand that it is a violation of Nevada law to falsify this application, and sanc ions may be imposed for fraud or misrepresenta ion. I affirm that I have read this applica ion and the statements made are true and correct. I understand and will comply with the guidelines of the Centers for Disease Control and Prevention concerning he preven ion of transmission of infectious agents through safe injec ion practices. I understand that NRS 432B.220 requires that if, in my professional capacity, I know or have reason to believe that a child has been abused or neglected, I am mandated to report he abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Signature : HaiDuong Ngo Date Of Application : 10/28/2023

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2023 to 10/31/2025	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0 00
	Total :	**$210.00**

Fee and Payment

Payment Me hod :	Credit / Debit Card
Application Fees :	200
Reinstatement Fee :	0
Transac ion Fee :	10
Late Fees :	0
Reference Number :	120083113498
InvoiceDate :	10/28/2023

Paid

Pay & Submit

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

TOP DRUGS PHARMACY, INC., dba
TOP DRUGS PHARMACY;
TOM THUY PHUNG, CEO, CFO, PRES, DIR, SEC, TREAS;
HAIDUONG NGO, VP, DIR,
Pharmacy Permit No. PHY 55878;

HAIDUONG NGO,
Pharmacist License No. RPH 54675;

and

TOM THUY PHUNG,
Pharmacist License No. 52739

Respondents.

Agency Case No. 7025

OAH No. 2021061004

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on April 21, 2022.

It is so ORDERED on March 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
CARL M. SONNE
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Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **TOP DRUGS PHARMACY, INC.,** **DBA TOP DRUGS PHARMACY;** **TOM THUY PHUNG, CEO, CFO, PRES, DIR, SEC, TREAS;** **HAIDUONG NGO, VP, DIR** **11010 Magnolia St.,** **Garden Grove, CA 92841** **Pharmacy Permit Number No. PHY 55878,** **HAIDUONG NGO** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 54675,** **and** **TOM THUY PHUNG** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 52739** Respondents.	Case No. 7025 OAH No. 2021061004 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO HAIDUONG NGO, ONLY**

IT IS HEREBY STIPULATED AND AGREED by and between parties Complainant Anne Sodergren and Respondent Haiduong Ngo to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Erin M. Sunseri, Supervising Deputy Attorney General.

2. Respondent is represented in this proceeding by Adam B. Brown of the Law Offices of Brown & Brown, 3848 Carson Street, Suite 206, Torrance, California 90503.

3. On or about August 21, 2003, the Board of Pharmacy issued Pharmacist License Number RPH 54675 to Haiduong Ngo (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2023, unless renewed.

JURISDICTION

4. Accusation No. 7025 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on February 1, 2021. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7025 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7025. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine

the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 7025, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up her right to contest those charges.

11. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 54675 issued to Respondent Haiduong Ngo is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves

Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Respondent's compliance with the terms and conditions of her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

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5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7025 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) her direct supervisor, (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7025, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the board in

writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7025, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 7025, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether Respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other

compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the board its costs of investigation and prosecution in the amount of $15,000.00 and shall be jointly and severally liable for those costs with Respondents Tom Thuy Phung and Top Drugs Pharmacy, Inc., dba Top Drugs Pharmacy. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If Respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

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12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish her license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume

practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 7025 shall be deemed true and correct.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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16. **Remedial Education**

Within thirty (30) days of the effective date of this decision, Respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to corresponding responsibility. The program of remedial education shall consist of at least ten hours completed each year of probation. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require Respondent, at her own expense, to take an approved examination to test Respondent's knowledge of the course. If Respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

17. **Board's One-Day Training Program**

Within the first year of probation, Respondent shall enroll in the Board's one-day, six (6) hour training program, "Preventing Prescription Drug Abuse and Drug Diversion," at Respondent's expense. Respondent shall provide proof of enrollment upon request. Within thirty (30) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in the training program, to initiate the training program during the first year of probation, to successfully complete it before the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

18. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by the board or its

designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered a violation of probation.

19. **Supervised Practice**

Within thirty (30) days of the effective date of this decision, Respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist by and not on probation with the board, to serve as Respondent's practice supervisor. As part of the documentation submitted, Respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 7025, and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to Respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, Respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision Respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist by and not on probation with the board, to serve as Respondent's replacement practice supervisor. As part of the documentation submitted, Respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 7025, and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by Respondent and shall be considered a violation of probation:

Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;

Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;

Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or

Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

During any suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, Respondent shall not engage in any activity that requires the professional judgment and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any suspension shall be considered a violation of probation.

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20. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Adam B. Brown. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

HAIDUONG NGO
Respondent

I have read and fully discussed with Respondent Haiduong Ngo the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

ADAM B. BROWN
Attorney for Respondent

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20. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Adam B. Brown. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/30/2021 Hai Duong Ngo

HAIDUONG NGO
Respondent

I have read and fully discussed with Respondent Haiduong Ngo the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12-30-21

ADAM B. BROWN
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
CARL M. SONNE
Senior Assistant Attorney General

ERIN M. SUNSERI
Supervising Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: 12/30/21

Respectfully submitted,

ROB BONTA
Attorney General of California
CARL M. SONNE
Senior Assistant Attorney General

ERIN M. SUNSERI
Supervising Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7025

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Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
ERIN M. SUNSERI
Deputy Attorney General
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Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 7025
TOP DRUGS PHARMACY, INC., **DBA TOP DRUGS PHARMACY;** **TOM THUY PHUNG, CEO, CFO, PRES, DIR, SEC, TREAS;** **HAIDUONG NGO, VP, DIR** **11010 Magnolia St.,** **Garden Grove, CA 92841** **Pharmacy Permit Number No. PHY 55878,** **HAIDUONG NGO** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 54675,** **and** **TOM THUY PHUNG** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 52739** Respondents.	**ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about August 21, 2003, the Board of Pharmacy issued Pharmacy Permit Number PHY 55878 to Top drugs Pharmacy, Inc., dba Top Drugs Pharmacy (Respondent Top Drugs Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2022, unless renewed.

3. On or about January 21, 2003, the Board of Pharmacy issued Pharmacist License Number RPH 54675 to Haiduong Ngo (Respondent Ngo). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2021, unless renewed.

4. On or about September 4, 2001, the Board of Pharmacy issued Pharmacist License Number RPH 52739 to Tom Thuy Phung (Respondent Phung). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2021, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 11000 *et seq*.).

7. Code section 4300, subdivision (a), provides that every license issued by the Board may be suspended or revoked.

8. Code section 4300.1 states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____" "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Code section 4113, subdivision (c) states:

The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

11. Code section 4301 states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

…

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

…

12. Code section 4306.5, subdivisions (a) and (b) states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient specific information pertaining to the performance of any pharmacy function.

13. Code section 4307, subdivision (a) states:

Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

14. Health and Safety Code section 11153, subdivision (a), states:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or

habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

REGULATORY PROVISIONS

15. Code of Federal Regulations, Title 21, section 1306.04, subdivision (a), states:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

16. California Code of Regulations, title 16, section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

COST RECOVERY

17. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUGS

18. Xanax is the brand name for alprazolam, a Schedule IV controlled substance pursuant to Health and Safety Code section 11057, subdivision (d)(1), and is a dangerous drug as defined by Business and Professions Code section 4022.

19. Adderall is the brand name for amphetamine salts, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (d)(1) and a dangerous drug as defined by Business and Professions Code section 4022.

20. Norco/Lortab is the brand name for hydrocodone/acetaminophen (APAP), a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (I)(i), and Title 21 CFR 1308.12 and a dangerous drug as defined by Business and Professions Code section 4022.

21. Percolone/Roxicodone is the brand name for oxycodone, a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(M) and a dangerous drug as defined by Business and Professions Code section 4022.

22. Phenergan with Codeine Syrup is the brand name for promethazine/codeine syrup, a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1) and a dangerous drug as defined by Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

23. At all relevant times, Respondent Top Drugs Pharmacy was an independent community pharmacy located in Garden Grove, California. At all relevant times, Respondent Ngo was the Pharmacist-in-Charge and owner of 25% of Respondent Top Drugs Pharmacy, and Respondent Phung was the owner of 75% of Respondent Top Drugs Pharmacy.

24. On or about February 13, 2020, a Board of Pharmacy inspector conducted an inspection of Top Drugs Pharmacy. Respondent Ngo, pharmacist-in-charge, was present during the inspection. Based on the facts set forth below, their educational and professional background and knowledge of pharmacy and drug laws, the Board's inspectors found a pattern of dispensing controlled substance prescriptions with red flags of illegitimacy, and determined that on numerous occasions, Respondents failed to exercise their corresponding responsibility and best professional judgment to dispense only controlled substance prescriptions issued for legitimate medical purposes.

25. The inspectors focused on five prescribers, Dr. E.D., Dr. J.D., Dr. S.C., Dr. A.F., and Physician Assistant (PA) J.E. The inspector found those prescribers' prescriptions contained

significant irregularities and "red flags," suggesting that prescriptions were not written or filled for a legitimate medical purpose. Respondents' prescribing profiles for these physicians indicated that alprazolam, amphetamine salts, promethazine with codeine and/or oxycodone 30 mg immediate-release, drugs associated with high rates of abuse and diversion, were the most commonly prescribed drugs for these prescribers. Most, if not all of the prescriptions from these prescribers exhibited obvious red flags of drug abuse that Respondents ignored when filling them, in spite of the Respondents' corresponding responsibility to ensure that all prescriptions dispensed were for a legitimate medical purpose.

Those red flags included:

Multiple patients at the same or similar address;

Cash payments;

Prescriptions written for an unusually large quantity of drugs;

Prescriptions written for potentially duplicative drugs;

The same combinations of drugs prescribed for multiple patients;

Initial prescriptions written for strong opiates;

Long distances traveled from the patient's home to the prescriber's office or pharmacy;

Irregularities in the prescriber's qualifications in relation to the medication(s) prescribed;

Prescriptions that are written outside of the prescriber's medical specialty;

Prescriptions for medications with no logical connection to diagnosis or treatment.

26. From January 22, 2018 through April 30, 2020, Respondents dispensed 10,298 prescriptions for non-controlled substances, comprising 90.3% of the total prescriptions dispensed. With many more medical conditions requiring treatment with non-controlled medications than controlled medications, this distribution is expected for a community pharmacy such as Respondent Top Drugs Pharmacy. The low percentages of controlled substance prescriptions dispensed would cause patterns of irregularities from particular prescribers to stand out, especially if multiple identical or similar prescriptions were presented on the same day, or

close to the same day. Of the top ten drugs (controlled and non-controlled) dispensed by Respondent Top Drugs Pharmacy, oxycodone 30 mg was the third most commonly dispensed, with a total amount paid by patients (out-of-pocket price) of $84,439. The second highest total amount paid by patients (out-of-pocket price) was $925.00, for ibuprofen 600 mg. The top five highest cash pay drugs dispensed by Respondent Top Drugs Pharmacy were oxycodone 30 mg, amphetamine salts 30 mg, promethazine/codeine syrup (ml), Narcan 4 mg spray, and alprazolam 2 mg. The percentage of cash payment for controlled substances dispensed by Respondent Top Drugs Pharmacy was more than three to five times that of non-controlled substances. This high percentage of cash payment for controlled substances was irregular for a retail pharmacy.

27. Top Drugs Pharmacy dispensed the following:

Oxycodone:

Drug	Number of prescriptions	Percent of total	Number with cash payment	Percent with cash payment
oxycodone 5 mg	0	0	0	0%
oxycodone 10 mg	1	0.5%	0	0%
oxycodone 15 mg	32	14.5%	0	0%
oxycodone 20 mg	4	1.8%	1	25%
oxycodone 30 mg	**183**	**83.2%**	**165**	**90.2%**
Total	**220**		**166**	

Oxycodone 30 mg prescriptions stood out as a group as having the following irregularities:

Higher percentage of oxycodone 30 mg compared to lower strengths;

Higher cash payment percentage for 30 mg strength than lower strengths of oxycodone, and more than most other controlled substances;

Large amounts of money charged to patients for these prescriptions, more than any other drug.

Alprazolam

Drug	Number of prescriptions	Percent of total	Number with cash payment	Percent with cash payment
alprazolam 0.25 mg	3	3.1%	0	0%
alprazolam 0.5 mg	10	10.2%	0	0%
alprazolam 1 mg	10	10.2%	0	0%
alprazolam 2 mg	**75**	**76.5%**	**73**	**97.3%**
Total	**98**		**73**	

Alprazolam 2 mg prescriptions stood out as a group as having the following irregularities:

Higher percentage of alprazolam 2 mg compared to lower strengths;

Higher cash payment percentage for 2 mg strength than lower strengths of alprazolam, and more than most other controlled substances.

Amphetamine salts

Drug	Number of prescriptions	Percent of total	Number with cash payment	Percent with cash payment
Amphetamine salts 30 mg	68	100%	68	100%

Amphetamine salts 30 mg prescriptions stood out as a group as having the following irregularities:

Only the highest available strength was dispensed;

All were from one prescriber;

All were for cash payment.

28. Dosing for oxycodone, alprazolam, and amphetamine salts was inconsistent with the principles of safe dosing, and titrating patients individually up from the lowest effective dose. This factor of irregularity would need to be resolved before dispensing controlled substances in the highest strengths, particularly if other red flags of illegitimacy existed. These patterns of irregularities from particular prescribers would stand out, especially if multiple identical or similar prescriptions were presented on the same day, or in the same time periods.

29. The above highest strength controlled substances, as well as promethazine/codeine, are very well known to be commonly sought after for abuse. The following prescribers contributed to the vast majority of these drugs dispensed by Respondent Top Drugs Pharmacy:

Prescriber	Drug	Number of prescriptions	Percent of total prescriptions dispensed of these drugs from each prescriber
Dr. S.C.	oxycodone 30 mg	31	16.9%
Dr. J.D.	oxycodone 30 mg	53	29.0%
Dr. E.D.		62	82.7%
		68	100%
PA J.E.	alprazolam 2 mg	11	14.7%

	oxycodone 30 mg	55	30.1%
	promethazine-codeine	98	87.5%
Dr. A.F.	oxycodone 30 mg	42	23.0%
	promethazine-codeine	8	7.1%

Just these five prescribers accounted for the following totals:

Drug	Number of prescriptions	Total percent of prescriptions dispensed from above prescribers
Oxycodone 30 mg	183	98.9%
Amphetamine salts 30 mg	68	100%
Promethazine/codeine syrup	112	94.6%
Alprazolam 2 mg	73	97.3%

30. From January 22, 2018 through April 30, 2020, Respondents dispensed **436** prescriptions for controlled substances under the prescribing authority of the above five prescribers. Having nearly all of these commonly sought drugs of abuse prescribed by just these five prescribers was a factor of irregularity.

PA J.E.

31. PA J.E. prescribed, and Respondents dispensed, the following: 29,019 mL of promethazine with codeine; 6,370 tablets of oxycodone immediate-release 30 mg; 900 tablets of alprazolam 2 mg; and 480 tablets of hydrocodone/APAP 10/325 mg. The two most common controlled substances prescribed by PA J.E. and dispensed by Respondents were promethazine/codeine and oxycodone 30 mg (the highest immediate release tablet available).

32. The uniformity of treatment is very irregular. There is patient variability in medical conditions, with not all being of the same cause, and thus requiring a variety of treatments. There was no adjustment in the oxycodone prescribing pattern from PA J.E. for age, weight, diagnosis,

drug allergies, medical histories, the severity of symptoms being treated, tolerance to drugs, or other patient related factors.

33. The patterns of controlled substances dispensed, per prescriptions from PA J.E., by Respondents, presented at least the following factors of irregularity, and contrasted with legitimate prescribing and dispensing of controlled substances:

All oxycodone prescriptions were for 30 mg, the highest strength available;

All controlled substance prescriptions were for cash payment;

23 of the 30 patients (76%) were prescribed oxycodone 30 mg;

25 of the 30 patients (83%) were prescribed promethazine/codeine;

Uniformity of treatment for multiple patients receiving similar or identical controlled substances on the same day;

Multiple patients dispensed overlapping treatment with oxycodone and promethazine/codeine, for which there is a boxed warning of serious risks;

Multiple patients dispensed overlapping treatment with oxycodone and alprazolam, for which there is a boxed warning of serious risks;

Numerous patients were repeatedly prescribed promethazine/codeine (indicated for the temporary relief of cough), some with full pint bottles, paying up to $200.00 cash for a bottle of cough syrup.

Dr. J.D.

34. Dr. J.D. prescribed, and Respondents dispensed, 4,950 tablets of oxycodone immediate-release 30 mg. The only controlled substance prescribed by Dr. J.D. and dispensed by Respondents was oxycodone 30 mg. This drug is very well known to be sought for abuse. Most irregular were the following factors:

20 out of 20 (100%) of the oxycodone prescriptions were for 30 mg, the highest strength available;

20 out of the 20 different patients from Dr. J.D. were prescribed oxycodone;

All were for cash payment, with some patients paying as much $720.00 for their prescription,

35. The uniformity of treatment is very irregular. There is patient variability in medical conditions, with not all being of the same cause, and thus requiring a variety of treatments. Due to the various presentations of pain symptoms, medications with differing mechanisms of actions are typically prescribed for the legitimate treatment of pain. There was no adjustment in the prescribing pattern from Dr. J.D. for age, weight, diagnosis, drug allergies, medical histories, the severity of symptoms being treated, tolerance to drugs, or other patient related factors.

Dr. A.F.

36. Dr. A.F. prescribed, and Respondents dispensed, the following: 1,920 mL of promethazine with codeine; 3,860 tablets of oxycodone immediate-release 30 mg; 84 tablets of oxycodone immediate-release 20 mg; and 120 tablets of hydrocodone/APAP 10/325 mg.

37. The uniformity of treatment is very irregular. There is patient variability in medical conditions, with not all being of the same cause, and thus requiring a variety of treatments. Due to the various presentations of pain symptoms, medications with differing mechanisms of actions are typically prescribed for legitimate treatment of pain. There was almost no adjustment in the oxycodone prescribing pattern from Dr. A.F. for age, weight, diagnosis, drug allergies, medical histories, the severity of symptoms being treated, tolerance to drugs, or other patient related factors.

38. The patterns of controlled substances dispensed per prescriptions from Dr. A.F. by Respondents, presented at least the following factors of irregularity, and contrasted with legitimate prescribing and dispensing of controlled substances:

42 of the 43 oxycodone prescriptions were for 30 mg, the highest strength available;

22 of the 27 different patients from Dr. A.F. were prescribed oxycodone 30 mg;

Over 80% of the prescriptions were paid with cash;

Sudden influx for multiple patients for the same drug;

Dr. S.C.

39. Dr. S.C. prescribed, and Respondents dispensed, 3,510 tablets of oxycodone immediate-release 30 mg.

40. The uniformity of treatment is very irregular. There is patient variability in medical conditions, with not all being of the same cause, and thus requiring a variety of treatments. Due to the various presentations of pain symptoms, medications with differing mechanisms of actions are typically prescribed for legitimate treatment of pain. There was no adjustment in the oxycodone prescribing pattern from Dr. S.C. for age, weight, diagnosis, drug allergies, medical histories, the severity of symptoms being treated, tolerance to drugs, or other patient related factors.

41. The patterns of controlled substances dispensed per prescriptions from Dr. S.C. by Respondents, presented at least the following factors of irregularity, and contrasted with legitimate prescribing and dispensing of controlled substances:

All of the oxycodone prescriptions were for 30 mg, the highest strength available;

All 10 different patients from Dr. S.C. were prescribed oxycodone 30 mg;

Over 74% of the prescriptions were paid with cash, with some patients paying as much $720.00 for their prescription;

It is irregular for a family and sports medicine doctor to prescribe oxycodone to all patients.

Dr. E.D.

42. Dr. E.D. prescribed, and Respondents dispensed, the following: 6,120 tablets of amphetamine salts 30 mg, and 5,730 tablets of alprazolam 2 mg.

43. The patterns of controlled substances dispensed per prescriptions from Dr. E.D. by Respondents, presented at least the following factors of irregularity, and contrasted with legitimate prescribing and dispensing of controlled substances:

All of the prescriptions were for the highest strengths available; All 15 different patients were prescribed amphetamine salts 30 mg; All 15 different patients were prescribed to take three tablets daily; 14 of the 15 patients were also prescribed alprazolam 2 mg;

All were for cash payment.

44. Additionally, amphetamine salts is to be labeled to be dosed in two to three divided doses. All of the amphetamine salts prescriptions were written by Dr. E.D., and dispensed, with

instructions to take three tablets daily. There were no notes or other documentation to indicate if the prescriber wrote this in error, and actually meant to prescribe one tablet three times per day. These patients could reasonably assume this meant to take the three tablets all at once, once per day, especially since all but one patient were also prescribed alprazolam 2 mg with contrasting directions to take one tablet three to four times per day. This is exactly the type of intervention which should have occurred in the usual course of professional pharmacy practice to prevent patients from taking drugs incorrectly; however, Respondents failed to intervene.

45. Many patients being treated by Dr. E.D. were also apparently treated with oxycodone and promethazine/codeine.

46. The uniformity of treatment is very irregular. There is patient variability in medical conditions, with not all being of the same cause, and thus requiring a variety of treatments. Due to the various presentations of pain symptoms, medications with differing mechanisms of actions are typically prescribed for legitimate treatment of pain. There was almost no adjustment in the oxycodone prescribing pattern from Dr. E.D. for age, weight, diagnosis, drug allergies, medical histories, the severity of symptoms being treated, tolerance to drugs, or other patient related factors.

47. It was a factor of irregularity for multiple patients from one prescriber to also receive treatment with interacting drugs from other prescribers. There was no indication or documentation to show any attempts to ensure this type of treatment was legitimate and being coordinated with all involved prescribers, despite exhibiting the following irregularities:

Identical, or similar addresses for many patients;

Identical or similar treatments for ADHD, anxiety, pain, and cough for many patients;

11 of the 15 patients were also dispensed prescriptions from PA Edwards.

48. Respondents dispensed controlled substances without ensuring they were for a legitimate medical use when obvious, objective, and systemic signs of irregularities and red flags of illegitimacy existed as detailed above.

49. Respondents dispensed controlled substances even though customers from certain prescribers paid for a large percentage of these medications in cash even though pharmacists

know that almost all patients seek reimbursement from insurance companies or government agencies for medications.

50. Although there are no restrictions or limits in pharmacy law for the price charged by drugs for pharmacies, the cash price for oxycodone 30 mg (up to $540.00 for 90 tablets, and $720.00 for 120 tablets) charged by Respondent Top Drugs Pharmacy appears to be much higher than amounts charged by other pharmacies. This would make the irregularity of cash payment particularly stand out as multiple patients paid large sums of money for certain controlled substances.

51. Normal pricing structures at pharmacies have the same price for a drug, regardless of the prescriber. Between September and December of 2019, Respondent Top Drugs Pharmacy charged patients of Dr. S.C. $2.00 per tablet on cash prescriptions for oxycodone 30 mg; however, Respondent charged patients of Dr. J.D. and Dr. A.F. $6.00 per tablet on cash prescriptions for oxycodone 30 mg. Charging three times as much for oxycodone 30 mg from certain prescribers is a factor of irregularity for these prescriptions.

52. Respondents filled prescriptions in which patients received oxycodone 30 mg tablets at dosages which were at least twice the recommended starting, or restarting, dose. The CURES reports showed that these patients had not received an opioid over a time, and in an amount, which would make appropriate dosing with oxycodone 30 mg to patients who were not opioid tolerant.

53. Respondents are required to maintain records of all prescriptions dispensed, and a review of prescriptions written by the prescribers detailed above would have been possible. Respondents failed to review the readily available patient and prescription records which would supply necessary information to use their best professional judgment in making appropriate dispensing decisions. When the sudden influx of these prescriptions occurred at Respondent Top Drugs Pharmacy, reasonable and prudent pharmacists would have had enough objective information to identify these prescriptions as not being issued in the usual course of professional practice. These prescriptions were exactly as would be expected for illegitimate prescriptions.

54. The data illustrated that Respondents failed to fulfill their corresponding responsibility by dispensing the following excessive amounts of controlled substances:

Totals dispensed from prescribers with red flags of illegitimacy

Drug	Number of prescriptions	Number of doses
alprazolam 2 mg	73	6,630
amphetamine 30 mg	68	6,120
oxycodone 30 mg	181	18,690
Promethazine/codeine (5 ml/dose)	106	6,187
Total	**428**	**37,627**

These prescriptions were presented with many factors of irregularity and red flags of illegitimacy, and Respondents failed to use available records and professional judgment when dispensing these controlled substances. The objective factors included but were not limited to:

Cash payment for controlled substances was three to five times more common than non-controlled substances;

Oxycodone 30 mg was the third most common drug (including non-controlled) dispensed;

Over six times as much money paid by patients for oxycodone 30 mg than any other drug;

Oxycodone 30 mg accounted for much more (83%) compared to lower strengths of oxycodone;

Oxycodone 30 mg cash payment was much more (90%) compared to lower strengths of oxycodone;

Oxycodone 30 mg cash price was three times higher for certain prescribers from September through December, 2019;

Oxycodone 30 mg was dispensed to the vast majority (76-100%) of patients from certain prescribers;

Higher percentage of alprazolam 2 mg (76%) compared to other lower strengths;

Higher cash payments for alprazolam 2 mg (97%) compared to other lower strengths;

Amphetamine 30 mg was the only strength dispensed, no lower strengths;

Amphetamine 30 mg was only dispensed for cash payment;

All patients from one prescriber treated with amphetamine, with only the highest 30 mg strength;

Commonly sought drugs of abuse predominately (94-100%) prescribed by just a few prescribers;

Promethazine/codeine dispensed to vast majority (83%) of patients from one prescriber;

Commonly sought drugs of abuse dispensed with other interacting controlled substances, including oxycodone with promethazine/codeine, and oxycodone with alprazolam;

Multiple patients receiving similar or identical treatment with promethazine/codeine on the same days;

Sudden influx of commonly sought drugs of abuse from certain prescribers with red flag patterns;

Uniformity of treatment for many patients, with no individually based treatment;

17 patients restarted on at least over twice the safe starting dose of oxycodone on 19 occasions.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Gross Negligence Against All Respondents)

55. Respondents are subject to disciplinary action under Code sections 4301, subdivision (c), in that Respondents owned, managed, and operated Top Drugs Pharmacy in an unprofessional manner with the inappropriate exercise, training, or experience and best professional judgment in that they:

a. Dispensed, or allowed to be dispensed, controlled substance prescriptions and ignored, or wasn't aware of, objective signs of irregularity and abuse;

b. Dispensed, or allowed to be dispensed, controlled substance prescriptions without ensuring they were issued for a legitimate medical purpose and the usual course of professional practice;

c. Failed to consult appropriate patient, prescription, and other records to prevent the dispensing of illegitimate prescriptions.

56. As described above, Respondents repeatedly furnished prescriptions for controlled substances even though obvious and systemic "red flags" were present to indicate those prescriptions were not issued for a legitimate medical purpose. Respondents' conduct was a gross deviation from the standard of safe pharmacy practice, and could cause harm to patients or other persons.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Excessive Prescribing Against All Respondents)

57. Respondents are subject to disciplinary action under Code sections 4301, subdivision (d), for violating Health and Safety Code section 11153, subdivision (a), for the clearly excessive furnishing of controlled substances, as follows:

a. Dispensed, or allowed to be dispensed, controlled substance prescriptions and ignored, or wasn't aware of, objective signs of irregularity and abuse;

b. Dispensed, or allowed to be dispensed, controlled substance prescriptions without ensuring they were issued for a legitimate medical purpose and the usual course of professional practice;

c. Failed to consult appropriate patient, prescription, and other records to prevent the dispensing of illegitimate prescriptions.

58. As described above, Respondents repeatedly furnished prescriptions for controlled substances even though obvious and systemic "red flags" were present to indicate those prescriptions were not issued for a legitimate medical purpose.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Failing to Comply with Corresponding Responsibility for Controlled Substance Prescriptions Against All Respondents)

59. Respondents are subject to disciplinary action under Code sections 4301, subdivisions (j) and (o), for violating Health and Safety Code section 11153, subdivision (a), and Code of Federal Regulations, Title 21, section 1306.04, subdivision (a), because they failed to comply

with their corresponding responsibility to ensure that controlled substances were dispensed for a legitimate medical purpose. As described above, Respondents repeatedly furnished prescriptions for controlled substances even though obvious and systemic "red flags" were present to indicate those prescriptions were not issued for a legitimate medical purpose.

FOURTH CAUSE FOR DISCIPLINE

(Failing to Exercise or Implement Best Professional Judgment or Corresponding Responsibility when Dispensing Controlled Substances Against Respondents Haiduong Ngo and Tom Thuy Phung)

60. Respondents Haiduong Ngo and Tom Thuy Phung are subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivisions (a) and (b), because they failed to exercise or implement their best professional judgment or corresponding responsibility when dispensing controlled substances, as described above.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct against All Respondents)

61. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct because they engaged in the activities described above.

OTHER MATTERS

62. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 55878 issued to Top Drugs Pharmacy, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55878 is placed on probation or until the Pharmacy Permit is reinstated if it is revoked.

63. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 55878 issued to Top Drugs Pharmacy, while Haiduong Ngo has been an owner or manager and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, she shall be prohibited from serving as a manager, administrator, owner, member,

officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked.

64. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 55878 issued to Top Drugs Pharmacy while Tom Thuy Phung has been an owner or manager and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked.

65. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 54675 issued to Haiduong Ngo, she shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

66. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 52739 issued to Tom Thuy Phung, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Permit Number PHY 55878, issued to Top Drugs Pharmacy Inc., dba Top Drugs Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 54675, issued to Haiduong Ngo;

3. Revoking or suspending Pharmacist License Number RPH 52739, issued to Tom Thuy Phung;

4. Prohibiting Top Drugs Pharmacy, Inc., dba Top Drugs Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55878 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;

5. Prohibiting Haiduong Ngo from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55878 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;

6. Prohibiting Tom Thuy Phung from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 55878 is placed on probation or until the Pharmacy Permit is reinstated, if it is revoked;

7. Prohibiting Haiduong Ngo from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 54675 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Prohibiting Tom Thuy Phung from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 52739 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

9. Ordering Top Drugs Pharmacy, Inc., dba Top Drugs Pharmacy, Haiduong Ngo and Tom Thuy Phung to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

10. Taking such other and further action as deemed necessary and proper.

DATED: 1/31/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

TOP DRUGS PHARMACY, INC., dba
TOP DRUGS PHARMACY;
TOM THUY PHUNG, CEO, CFO, PRES, DIR, SEC, TREAS;
HAIDUONG NGO, VP, DIR,
Pharmacy Permit No. PHY 55878;

HAIDUONG NGO,
Pharmacist License No. RPH 54675;

and

TOM THUY PHUNG,
Pharmacist License No. 52739

Respondents.

Agency Case No. 7025

OAH No. 2021061004

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on April 21, 2022.

It is so ORDERED on March 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **TOP DRUGS PHARMACY, INC.,** **DBA TOP DRUGS PHARMACY;** **TOM THUY PHUNG, CEO, CFO, PRES, DIR, SEC, TREAS;** **HAIDUONG NGO, VP, DIR** **11010 Magnolia St.,** **Garden Grove, CA 92841** **Pharmacy Permit Number No. PHY 55878,** **HAIDUONG NGO** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 54675,** **and** **TOM THUY PHUNG** **[redacted] Waterbury Ln.,** **Huntington Beach, CA 92646** **Pharmacist License No. RPH 52739** Respondents.	Case No. 7025 OAH No. 2021061004 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO HAIDUONG NGO, ONLY**

IT IS HEREBY STIPULATED AND AGREED by and between parties Complainant Anne Sodergren and Respondent Haiduong Ngo to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Erin M. Sunseri, Supervising Deputy Attorney General.

2. Respondent is represented in this proceeding by Adam B. Brown of the Law Offices of Brown & Brown, 3848 Carson Street, Suite 206, Torrance, California 90503.

3. On or about August 21, 2003, the Board of Pharmacy issued Pharmacist License Number RPH 54675 to Haiduong Ngo (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2023, unless renewed.

JURISDICTION

4. Accusation No. 7025 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on February 1, 2021. Respondent timely filed her Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7025 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7025. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine

the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 7025, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up her right to contest those charges.

11. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 54675 issued to Respondent Haiduong Ngo is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves

Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Respondent's compliance with the terms and conditions of her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

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5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7025 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) her direct supervisor, (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7025, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the board in

writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7025, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 7025, and the terms and conditions imposed thereby in advance of respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether Respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

8. **Restrictions on Supervision and Oversight of Licensed Facilities**

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other

compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the board its costs of investigation and prosecution in the amount of $15,000.00 and shall be jointly and severally liable for those costs with Respondents Tom Thuy Phung and Top Drugs Pharmacy, Inc., dba Top Drugs Pharmacy. Respondent shall be permitted to pay these costs in a payment plan approved by the board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If Respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

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12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish her license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume

practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 7025 shall be deemed true and correct.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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16. **Remedial Education**

Within thirty (30) days of the effective date of this decision, Respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to corresponding responsibility. The program of remedial education shall consist of at least ten hours completed each year of probation. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require Respondent, at her own expense, to take an approved examination to test Respondent's knowledge of the course. If Respondent does not achieve a passing score on the examination that course shall not count towards satisfaction of this term. Respondent shall take another course approved by the board in the same subject area.

17. **Board's One-Day Training Program**

Within the first year of probation, Respondent shall enroll in the Board's one-day, six (6) hour training program, "Preventing Prescription Drug Abuse and Drug Diversion," at Respondent's expense. Respondent shall provide proof of enrollment upon request. Within thirty (30) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in the training program, to initiate the training program during the first year of probation, to successfully complete it before the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

18. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by the board or its

designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered a violation of probation.

19. **Supervised Practice**

Within thirty (30) days of the effective date of this decision, Respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist by and not on probation with the board, to serve as Respondent's practice supervisor. As part of the documentation submitted, Respondent shall cause the proposed practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 7025, and is familiar with the terms and conditions imposed thereby, including the level of supervision required by the board or its designee. This level will be determined by the board or its designee, will be communicated to Respondent on or before the effective date of this decision and shall be one of the following:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Respondent may practice only under the required level of supervision by an approved practice supervisor. If, for any reason, including change of employment, Respondent is no longer supervised at the required level by an approved practice supervisor, within ten (10) days of this change in supervision Respondent shall submit to the board or its designee, for prior approval, the name of a pharmacist by and not on probation with the board, to serve as Respondent's replacement practice supervisor. As part of the documentation submitted, Respondent shall cause the proposed replacement practice supervisor to report to the board in writing acknowledging that he or she has read the decision in case number 7025, and is familiar with the terms and conditions imposed thereby, including the level of supervision required.

Any of the following shall result in the automatic suspension of practice by Respondent and shall be considered a violation of probation:

Failure to nominate an initial practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within thirty (30) days;

Failure to nominate a replacement practice supervisor, and to have that practice supervisor report to the board in writing acknowledging the decision, terms and conditions, and supervision level, within ten (10) days;

Practicing in the absence of an approved practice supervisor beyond the initial or replacement nomination period; or

Any failure to adhere to the required level of supervision.

Respondent shall not resume practice until notified in writing by the board or its designee.

During any suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During any suspension, Respondent shall not engage in any activity that requires the professional judgment and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances.

Failure to comply with any suspension shall be considered a violation of probation.

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20. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Adam B. Brown. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

HAIDUONG NGO
Respondent

I have read and fully discussed with Respondent Haiduong Ngo the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

ADAM B. BROWN
Attorney for Respondent

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20. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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DATED: 12/31/2021 Hai Duong Ngo

HAIDUONG NGO
Respondent

I have read and fully discussed with Respondent Haiduong Ngo the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12-30-21

ADAM B. BROWN
Attorney for Respondent

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
CARL M. SONNE
Senior Assistant Attorney General

ERIN M. SUNSERI
Supervising Deputy Attorney General
Attorneys for Complainant

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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: 12/30/21

Respectfully submitted,

ROB BONTA
Attorney General of California
CARL M. SONNE
Senior Assistant Attorney General

BRIN M. SUNSERI
Supervising Deputy Attorney General
Attorneys for Complainant

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11B

Back To Dashboard

Renewal Application
Pharmacist

Application Fee : $200.00
Convenience Fee : $10.00
License Number : 12186
License Type : Pharmacist
New Expiration Date : 10/31/2025

Renewal Type

Please confirm the status that you are renewing before moving to the next section.

(•) Ac ive ( ) Inactive [Proceed to Renew]

Personal Information

First Name : Roland
Middle (ini ial only) :
Last Name : Israel
License # : 12186

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA :
Military Address : [ ]
Street : [redacted] MARYLAND DR
Country : United States
City : LOS ANGELES State : California Zip : 90048
Practice Phone : (XXX) XXX-XXXX Practice Fax : (XXX) XXX-XXXX

[ ] Select if the Practice Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Home Address :

Military Address : [ ]
Street : [redacted] maryland drive
Country : United States
City : Los Angeles State : California Zip : 90048
Home Phone : [redacted] Cell Phone : [redacted]
Email Address : [redacted] Fax : (XXX) XXX-XXXX

[x] Select if he Home Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Sex : Male
Practice License Number:
Specialty:

Nevada Business License Information - Check appropriate answer

- (●) **I DO NOT** have a Nevada Business license number.
- ( ) **I HAVE APPLIED** for a Nevada Business License with he Nevada Secretary of State in Compliance with provisions of NRS Chapter 76 and my applica ion is pending.
- ( ) I have a Nevada Business License number assigned by the Secretary of State in compliance with he provisions of NRS Chapter 76789066.

Name on Business License :

Business License # :

Child Support Information – Check appropriate answer

- (●) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to he order.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or o her public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in he Armed Forces of the United States and separated from such service under condi ion o her than dishonorable	( ) Yes (●) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions o her than dishonorable	( ) Yes (●) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the Na ional Oceanic and Atmospheric Administration of the United States in the capacity of he commissioned officer while on active duty in defense of the United States and separated from such service under conditions o her than dishonorable?	( ) Yes (●) No

Legal Information

3918

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whe her completed or pending in any state? ◉ Yes ○ No

Stipulated settlement

Document Name	Document Type	Date	Link	Action
AC case 7042	Legal - Question 3	10/19/2023	Document Details	

Document Name : Document Type : Legal - Ques ion 3

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select Date : 08/04/2022

Case # : ac 7042

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ◉ Yes ○ No

stipulated settlement

Document Name	Document Type	Date	Link	Action
AC 7042	Legal - Question 4	10/19/2023	Document Details	

Document Name : Document Type : Legal - Ques ion 4

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select Date : 08/04/2022

Case # : ac case 7042

Criminal Action :

State : Select Date : MM/DD/YYYY

Case # :

County : Court :

CE Hours

Active ☑ By checking his box you certify you have completed ALL required CE Hours due for the 2021/2023 Renewal period. (Dated from Nov. 1, 2021 – Oct. 31, 2023; 1.25hrs per mo). The exemp ion period is 2yrs after graduation only

Acknowledgement and Declaration

I understand that it is a violation of Nevada law to falsify this application, and sanc ions may be imposed for fraud or misrepresentation. I affirm that I have read this applica ion and the statements made are true and correct. I understand and will comply with the guidelines of the Centers for Disease Control and Prevention concerning he preven ion of transmission of infec ious agents through safe injec ion prac ices. I understand that NRS 432B.220 requires that if, in my professional capacity, I know or have reason to believe that a child has been abused or neglected, I am mandated to report he abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Signature : Roland Israel

Date Of Application : 10/19/2023

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2023 to 10/31/2025	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0 00
	Total :	**$210.00**

Fee and Payment

Payment Me hod : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transac ion Fee : 10

Late Fees : 0

Reference Number : 120068651543

InvoiceDate : 10/19/2023

Paid

Pay & Submit

MATTHEW RODRIQUEZ
Acting Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General
SHERONDA L. EDWARDS
Deputy Attorney General
State Bar No. 225404
300 So. Spring Street, Suite 1702
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Telephone: (213) 269-6296
Facsimile: (916) 731-2126
E-mail: Sheronda.Edwards@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SCRIPTSRUS, CORP. DBA SCRIPTSRUS PHARMACY,** **ROLAND ISRAEL** **15630 Ventura Blvd** **Encino, CA 91436** **Pharmacy Permit No. PHY 52078,** **and** **ROLAND ISRAEL** **[redacted] Maryland Drive** **Los Angeles, CA 90048** **Pharmacist License No. RPH 47379,** Respondents.	Case No. 7042 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about December 1, 2014, the Board issued Permit Number PHY 52078 to Scriptsrus, Corp. dba Scriptsrus Pharmacy, Roland Israel (Respondent Scriptsrus). The Permit was

in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2021, unless renewed.

3. On or about August 5, 1994, the Board issued Pharmacist License Number RPH 47379 to Respondent Pharmacist-in-Charge, Roland Israel (Respondent Israel). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on June 30, 2022, unless renewed. Respondent Israel is and has been the Pharmacist-in-Charge, President, Partner, and Secretary of Respondent Scriptsrus since September 8, 2014.

JURISDICTION

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 118, subdivision (b), of the Code states that the suspension, expiration, surrender, cancellation of a license shall not deprive the Board, Registrar/Director of jurisdiction, to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

6. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

...

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final,

except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4302 of the Code states:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

9. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the

Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

BUSINESS AND PROFESSIONS CODE PROVISIONS

10. Section 4021 of the Code states:

"Controlled substance" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

11. Section 4022 of the Codes states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

...

12. Section 4113 of the Code states:

...

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

13. Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

14. Section 4301 of the Code states:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

...

15. Section 4306.5 of the Code states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

(d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

HEALTH AND SAFETY CODE PROVISIONS

16. Section 11152 of the Code states:

No person shall write, issue, fill, compound, or dispense a prescription that does not conform to this division.

17. Section 11153 of the Code states:

(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding

responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

...

18. Section 11162.1 of the Code states:

(a) The prescription forms for controlled substances shall be printed with the following features:

...

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

...

(6) A description of the security features included on each prescription form.

...

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

...

(15) A uniquely serialized number, in a manner prescribed by the Department of Justice in accordance with Section 11162.2.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

19. Section 11164 of the Code states:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1. ...

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STATE REGULATORY PROVISION

20. Section 1761 of the California Code of Regulations, title 16, states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

COST RECOVERY

21. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG CLASSIFICATIONS

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B&PC § 4022	CONTROLLED SUBSTANCE PER H&SC	INDICATIONS FOR USE
Xanax	Alprazolam	Yes	Yes – Schedule IV, H&SC § 11057(d)(1)	Anxiety
Adderall	Amphetamine Salts	Yes	Yes – Schedule II, H&SC § 11055(d)(1)	ADD/ADHD
Norco/Lortab	Hydrocodone/ Acetaminophen (APAP)	Yes	Yes – Schedule II, H&SC § 11055(l)(i) Yes – Schedule II, Title 21 CFR § 1308.12	Pain
Percolone/ Roxicodone	Oxycodone	Yes	Yes – Schedule II, H&SC § 11055(b)(1)(M)	Pain
Phenergan with Codeine Syrup	Promethazine/ Codeine Syrup	Yes	Yes, Schedule V, H&SC § 11058(c)(1)	Cough

FACTUAL ALLEGATIONS

22. On May 1, 2020, a Board Inspector emailed Respondent Israel a request for pharmacy records and original prescriptions for Respondent Scriptsrus. Subsequently, the Inspector received Respondent Scriptsrus' dispensing records for April 30, 2017 through April 30, 2020, and copies of prescription documents instead of originals. On June 10, 2020, the Inspector received the original prescriptions, after a second request, and unsolicited documents not previously provided.

Doctors MB, DB, and JK

23. The Board's investigation revealed that from June 29, 2017 through March 1, 2019, Respondent Scriptsrus and Respondent Israel (collectively Respondents) dispensed 63 controlled substance prescriptions from prescribers Dr. MB, Dr. DB, and Dr. JK on invalid security prescription forms for Alprazolam, Amphetamine Salts, and Oxycodone classified as Schedule IV controlled substances and Promethazine/Codeine classified as a Schedule V controlled substance, which were missing required features described as follows, but not limited to:

(a) Prescription documents were missing a watermark printed on the backside of the prescription, which reads: "California Security Prescription."

(b) Repeat sequential form numbers were used on some prescriptions.

(c) Dr. MB's prescriptions lacked a valid DEA number.

24. These prescriptions had enough red flags of illegitimacy to be recognized as the illegal distribution of controlled substances for diversion and abuse.

25. The Board's investigation also revealed that Respondents failed to exercise their corresponding responsibility from April 30, 2017 through April 30, 2020, as to 89 prescriptions of Alprazolam 2mg for 7,620 doses, 99 prescriptions of Amphetamine Salts 30 mg for 8,400 doses, 154 prescriptions of Oxycodone 30 mg for 14,880 doses, and 15 prescriptions of Promethazine/Codeine (5ml/dose) for 1,232 doses for a total number of 357 prescriptions and 37,063 total number of doses as described below.

26. Specifically, Respondents dispensed 63 controlled substance prescriptions from Dr. MB, Dr. DB, and Dr. JK after ignoring or failing to recognize multiple objective factors which

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showed the prescriptions were irregular and not medically legitimate prescriptions. The objective factors of illegitimacy, irregularity and abuse include, but were not limited to the following:

(a) Long distances traveled from patient homes in Van Nuys to prescribers Dr. MB's office in Santa Ana and Dr. DB's office in West Hollywood.

(b) Patients had appointments on the same day with prescribers in different cities.

(c) Patients issued the same prescriptions on the same day at different offices.

(d) Initial prescriptions were written for high starting doses described below:

i. 07/09/2018 for Oxycodone 30 mg, RX 106466, by Dr. DB, to patient NS.

ii. 10/03/2018 for Alprazolam 2 mg, RX 107321, by Dr. MB, to patient NS.

iii. 08/06/2018 for Oxycodone 30 mg, RX 106725, by Dr. DB, to patient RS.

27. Also, prescribers Dr. MB, Dr. DB, and Dr. JK only prescribed the highest strength of controlled substances[1] described below:

PRESCRIBER	DRUG	NUMBER OF RXS	TOTAL QUANTITY
MB	Alprazolam 2 mg	14	840
	Amphetamine Salts 30 mg	16	960
DB	Oxycodone 30 mg	17	2,040
JK	Alprazolam 2 mg	6	600
	Amphetamine Salts 30 mg	6	540
	Oxycodone 30 mg	4	480
	Total	**63**	**5,460**

28. These 63 fraudulent prescriptions had enough red flags of illegitimacy to be recognized as the illegal distribution of controlled substances. None of the prescription documents submitted indicated resolution of the irregularities of prescribing controlled substances.

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[1] Alprazolam is available in 0.25 mg to 2 mg immediate release tablets. Amphetamine Salts are available in various strengths from 5 mg to 30 mg immediate release tablets. Oxycodone is available in 5, 10, 15, 20, and 30 mg immediate release tablets.

Dr. JMK

29. In addition, the investigation revealed that from April 30, 2018 through April 30, 2020, Respondents dispensed 82 controlled substance prescriptions from prescriber Dr. JMK with patterns of irregularities and red flags of abuse without ensuring the prescriptions to patients VT, PF, AA, AB, SE, AE, FL, and RT were issued for a legitimate medical purpose in the usual course of professional practice. The objective factors of illegitimacy, irregularity and abuse include, but were not limited to the following:

(a) All 82 Oxycodone prescriptions for 7,160 tablets were for 30 mg, the highest strength available.

(b) Every patient was prescribed Oxycodone 30 mg without adjustment to varying patient demographic data.

30. These patterns are apparent deviations from the usual course of professional practice.

Physician Assistant JME

31. The investigation records further revealed that from January 31, 2019 through April 16, 2020, Respondents dispensed 212 controlled substances from prescriber Physician Assistant JME with patterns of irregularities and red flags of abuse without ensuring the prescriptions to patients JB, EM, SR, LF, NS, RF, JC, TA, PO, and IS were issued for a legitimate medical purpose in the usual course of professional practice, described as follows:

(a) All 51 Oxycodone prescriptions were for 30 mg for 5,200 tablets, the highest strength available.

(b) All 77 Amphetamine Salts prescriptions were for 30 mg for 6,900 tablets, the highest strength available.

(c) All 69 Alprazolam prescriptions were for 2 mg for 6,180 tablets, the highest strength available.

(d) High percentage of cash payments for controlled substances.

(e) Numerous patients prescribed Oxycodone, Amphetamine Salts, Alprazolam, and or Promethazine/Codeine in a pattern of overlapping treatment, for which there is a boxed warning of serious risks.

(f) Each of the 15 Promethazine/Codeine prescriptions was prescribed with Oxycodone 30 mg.

(g) Most of the 15 Promethazine/Codeine prescriptions were for 473 ml, a full pint size bottle.

(h) Multiple patients issued similar or identical controlled substances prescriptions on the same day regardless of patient demographic data.

32. These patterns are apparent deviations from the usual course of professional practice.

Initial Prescriptions Written for Strong Controlled Substances and Other Irregularities

33. Furthermore, the investigation revealed that from June 7, 2018 through March 18, 2020, Respondents dispensed controlled substance prescriptions from prescribers Dr. JMK, Dr. MB, Dr. DB, Dr. MG, and Dr. AF with the following additional patterns of irregularities and red flags of abuse:

(a) Prescriptions dispensed days and even weeks after the date prescribed.

(b) Cash payments.

(c) Patients were not tolerant to opioids.

(d) High Oxycodone doses greater than 90 MME/day.[2]

(e) High Alprazolam doses.

(f) High Amphetamine Salts doses.

(g) Out of area patients (between 25-50 miles away).

(h) Out of area prescribers (25 miles away).

(i) Patients JC and TA were dispensed almost identical prescriptions on the same day.

34. In addition, these eleven patients were dispensed unusually high doses at least twice the recommended safe dose of Oxycodone, Amphetamine Salts, and or Alprazolam without any documentation of effective intervention by a pharmacist. Also, ten of eleven patients were started or restarted on opioid doses above the CDC recommendation limit of 90 MME/day for opioids.

[2] According to the Centers for Disease Control and Prevention (CDC), higher opioid doses are associated with a higher risk of overdose and death. The concept of Morphine Milligram Equivalent (MME) has come into everyday use to facilitate dosing decisions. The CDC guidelines recommend caution when prescribing opioids at any dosage. Doses above 90 MME/day (60 mg/day of Oxycodone) should be avoided or carefully justified and titrated accordingly.

FIRST CAUSE FOR DISCIPLINE

(Requirements of Controlled Substance Prescriptions)

35. Respondent Scriptsrus and Respondent Israel are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code sections 11152, 11162.1 and 11164, in conjunction with California Code of Regulations, title 16, section 1761, in that Respondents dispensed controlled substances written on deficient and noncompliant prescription forms by prescribers Dr. MB, Dr. DB, and Dr. JK for a total of 63 prescriptions. Complainant refers to, and by reference, incorporates the allegations set forth above in paragraphs 22 through 24, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Failure to Exercise Corresponding Responsibility)

36. Respondent Scriptsrus and Respondent Israel are subject to disciplinary action under Code section 4301, subdivisions (c), (d), (j), and (o), and section 4306.5, in conjunction with the Health and Safety Code section 11153, subdivision (a), and California Code of Regulations, title 16, section 1761, in that between April 30, 2017 through April 30, 2020, Respondents operated in a grossly negligent manner, which constituted unprofessional conduct by excessively furnishing 357 prescriptions and 37,063 doses of controlled substances, despite multiple cues of irregularity and uncertainty related to patient and prescriber factors, and in failing to comply with their corresponding responsibility to ensure that controlled substances were dispensed for a legitimate medical purpose. Complainant refers to, and by this reference, incorporates the allegations set forth above in paragraphs 22 through 34, as though set forth fully.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Respondent Israel)

37. Respondent Israel is subject to disciplinary action under Code sections 4301, 4113, subdivision (c), and 4306.5, in that between April 30, 2017 through April 30, 2020, as the Pharmacist-in-Charge of Respondent Scriptsrus Pharmacy, Respondent Israel committed acts of unprofessional conduct when he failed to ensure that Respondent Scriptsrus exercised its corresponding responsibility to ensure the legitimacy of controlled substance prescriptions

dispensed. Respondent Israel approved to be dispensed 357 prescriptions and 37,063 doses of controlled substances, despite multiple cues of irregularity and uncertainty related to patient and prescriber factors, and failed to ensure that controlled substances were dispensed for a legitimate medical purpose. Complainant refers to, and by this reference, incorporates the allegations set forth above in paragraphs 22 through 34, as though set forth fully.

OTHER MATTERS

38. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 52078 issued to Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy, Roland Isreal, Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy, Roland Isreal shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 52078 is placed on probation or until Pharmacy Permit Number PHY 52078 is reinstated if it is revoked.

39. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacy Permit Number PHY 52078, issued to Scriptsrus, Corp. dba Scriptsrus Pharmacy, Roland Israel, for conduct that occurred while Respondent Israel, a Pharmacist-in-Charge, President, Partner, and Secretary, had knowledge of or knowingly participated in the conduct for which Respondent Scriptsrus was disciplined, then Respondent Israel shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 52078 is placed on probation or until Pharmacy Permit Number PHY 52078 is reinstated if it is revoked.

40. Pursuant to section 4307 of the Code, if discipline is imposed on Pharmacist License Number RPH 47379 issued to Roland Israel, Roland Isreal shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacist License Number RPH 47379 is placed on probation or until Pharmacist License Number RPH 47379 is reinstated if it is revoked.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the California State Board of Pharmacy issue a decision:

1. Revoking or suspending Permit Number PHY 52078, issued to Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy, Roland Israel;

2. Revoking or suspending Pharmacist License Number RPH 47379, issued to Roland Israel;

3. Prohibiting Scriptsrus Pharmacy Corp., dba Scriptsrus Pharmacy, Roland Israel from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 52078 is placed on probation or until Pharmacy Permit Number PHY 52078 is reinstated if Pharmacy Permit Number PHY 52078 issued to Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy, Roland Israel is revoked;

4. Prohibiting Roland Israel from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 52078 is placed on probation or until Pharmacy Permit Number PHY 52078 is reinstated if Pharmacy Permit Number PHY 52078 issued to Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy, Roland Isreal is revoked;

5. Prohibiting Roland Israel from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacist License Number RPH 47379 is placed on probation or until Pharmacist License Number RPH 47379 is reinstated if Pharmacist License Number RPH 47379 issued to Roland Isreal is revoked;

6. Ordering Scriptsrus Pharmacy, Corp. dba Scriptsrus Pharmacy and Roland Israel to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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7. Taking such other and further action as deemed necessary and proper.

DATED: 5/4/2021

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2021.05.04 22:09:57 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **SCRIPTSRUS CORP. DBA SCRIPTSRUS PHARMACY, ROLAND ISRAEL** **15630 Ventura Blvd.** **Encino, CA 91436** **Pharmacy Permit No. PHY 52078** **and** **ROLAND ISRAEL** **[redacted] Maryland Drive** **Los Angeles, CA 90048** **Pharmacist License No. RPH 47379** Respondents.	Case No. 7042 OAH No. 2021080317 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO SCRIPTSRUS CORP. DBA SCRIPTSRUS PHARMACY, PHARMACY PERMIT NO. 52078 ONLY**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by

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Rob Bonta, Attorney General of the State of California, by Sheronda L. Edwards, Deputy Attorney General.

2. Respondent Scriptsrus Corp. dba Scriptsrus Pharmacy, Roland Israel (Respondent) is represented in this proceeding by attorney Armond Marcarian, whose address is: Marcarian Law Firm, 21650 Oxnard Street, Suite 1980, Woodland Hills, CA 91367-7853.

3. On or about December 1, 2014, the Board issued Pharmacy Permit No. PHY 52078 to Respondent. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 7042, and will expire on December 1, 2022, unless renewed.

JURISDICTION

4. Accusation No. 7042 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on May 13, 2021. Respondent timely filed its Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7042 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7042. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 7042, if proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.

11. Respondent agrees that its Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary

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Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 52078 issued to Respondent Scriptsrus Corp. dba Scriptsrus Pharmacy, Roland Israel, is revoked. However, the revocation is stayed, and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. **Definition: Respondent**

For the purposes of these terms and conditions, "Respondent" shall refer to Scriptsrus Corp. dba Scriptsrus Pharmacy. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or

- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's Pharmacy Permit No. PHY 52078 or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any dangerous drug, and/or dangerous device or controlled substance. Failure to timely report any such occurrence shall be considered a violation of probation.

3. **Report to the Board**

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

4. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

5. **Cooperate with Board Staff**

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probationn.

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6. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall be jointly and severally responsible with Respondent Roland Israel to pay to the Board its costs of investigation and prosecution in the amount of $15,513.51. Respondent shall make said payments monthly to commence within thirty (30) days of the effective date of this Decision pursuant to the following terms:

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than three (3) years prior to the end date of probation.

7. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. **Status of License**

Respondent shall, at all times while on probation, maintain current Pharmacy Permit with the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent's Pharmacy Permit expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent's Pharmacy Permit shall be subject to all terms and conditions of this probation not previously satisfied.

9. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent wish to discontinue business, Respondent may tender the premises license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other

action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Respondent may not apply for any new license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

Upon acceptance of the surrender, Respondent shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

10. **Sale or Discontinuance of Business**

During the period of probation, should Respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to Respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the Board or its designee shall have the sole discretion to determine whether to exercise continuing

jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary, relief employees, and independent contractors employed or hired at any time during probation.

12. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **Premises Open for Business**

Respondent shall remain open and engaged in its ordinary business as a Pharmacy in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be

extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent is informed otherwise in writing by the Board or its designee. If Respondent is not open and engaged in its ordinary business as a Pharmacy for a minimum of 80 hours in any calendar month, for any reason (including vacation), Respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours Respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which Respondent will resume business as required. Respondent shall further notify the Board in writing with ten (10) days following the next calendar month during which Respondent is open and engaged in its ordinary business as a Pharmacy in California for a minimum of 80 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the Board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the Board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. **Violation of Probation**

If a Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and probation shall be automatically extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 7042 shall be deemed true and correct.

16. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's Pharmacy Permit will be fully restored.

17. **No Additional Ownership or Management of Licensed Premises**

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm, partnership, or corporation currently or hereinafter licensed by the Board except as approved by the Board or its designee. Violations of this restriction shall be considered a violation of probation.

17. **Consultant Review of Pharmacy Operations**

During the period of probation, Respondent Pharmacy shall retain an independent consultant at its own expense who shall be responsible for conducting an inspection to review the operations of Respondent Pharmacy on a monthly basis for compliance by Respondent Pharmacy with state and federal laws and regulations governing the practice of pharmacy, and compliance by Respondent. During the period of probation, the Board or its designee, retains the discretion to modify the frequency of the inspection of the pharmacist consultant's review.

The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision.

Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Armond Marcarian. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SCRIPTSRUS CORP. DBA SCRIPTSRUS PHARMACY, ROLAND ISRAEL
Respondent

I have read and fully discussed with Respondent Scriptsrus Corp. dba Scriptsrus Pharmacy, Roland Israel the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

ARMOND MARCARIAN
Attorney for Respondent

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Armond Marcarian. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 4-21-22

SCRIPTSRUS CORP. DBA SCRIPTSRUS PHARMACY, ROLAND ISRAEL
Respondent

I have read and fully discussed with Respondent Scriptsrus Corp. dba Scriptsrus Pharmacy, Roland Israel the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: April 22, 2022

ARMOND MARCARIAN
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General

SHERONDA L. EDWARDS
Deputy Attorney General
Attorneys for Complainant

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Back To Dashboard

Renewal Application
Pharmacist

Application Fee : $200.00
Convenience Fee : $10.00
License Number : 22166
License Type : Pharmacist
New Expiration Date : 10/31/2025

Renewal Type

Please confirm the status that you are renewing before moving to the next section.

(•) Ac ive ( ) Inactive [Proceed to Renew]

Personal Information

First Name : Tony
Middle (ini ial only) : Hieu
Last Name : La
License # : 22166

If you make an unnecessary change to your address, it will delay the processing of your renewal. Only make the change if it is a true address change. Example: Do not add punctuation or change St to Street.

Practice Address :

Name/Practice Name/DBA : Ameripharma
Military Address : [ ]
Street : 132 S Anita Dr 2nd Floor
Country : United States
City : Orange
State : California
Zip : 92868
Practice Phone : (XXX) XXX-XXXX
Practice Fax : (XXX) XXX-XXXX

[ ] Select if the Practice Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Home Address :

Military Address : [ ]
Street : [redacted] Veterans Way
Country : United States
City : Tustin
State : California
Zip : 92782
Home Phone : (XXX) XXX-XXXX
Cell Phone : [redacted]
Email Address : [redacted]
Fax : (XXX) XXX-XXXX

[x] Select if he Home Address is your mailing address

The address you select as the mailing address will be shown on the certificate

Sex : Male
Practice License Number:
Specialty:

Nevada Business License Information - Check appropriate answer

- (●) **I DO NOT** have a Nevada Business license number.
- ( ) **I HAVE APPLIED** for a Nevada Business License with he Nevada Secretary of State in Compliance with provisions of NRS Chapter 76 and my applica ion is pending.
- ( ) I have a Nevada Business License number assigned by the Secretary of State in compliance with he provisions of NRS Chapter 76789066.

Name on Business License :

Business License # :

Child Support Information – Check appropriate answer

- (●) I am **NOT SUBJECT** to a court order for the support of a child.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am in compliance with the order or am in compliance with a plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to he order.
- ( ) I am **SUBJECT** to a court order for he support of one or more children and am NOT in compliance with the order or am NOT in compliance with a plan approved by the district attorney or o her public agency enforcing the order for the repayment of the amount pursuant to the order.

Military Service Information

Have you ever served on active duty in he Armed Forces of the United States and separated from such service under condi ion o her than dishonorable	( ) Yes (●) No
Have you ever been assigned to duty for minimum of 6 continuous years in National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions o her than dishonorable	( ) Yes (●) No
Have you ever served the Commissioned Corp of the United States Public Service or the Commissioned Corp of the Na ional Oceanic and Atmospheric Administration of the United States in the capacity of he commissioned officer while on active duty in defense of the United States and separated from such service under conditions o her than dishonorable?	( ) Yes (●) No

Legal Information

3951

1. Since your last renewal or recent licensure have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license? ○ Yes ◉ No

2. Since your last renewal or recent licensure have you been charged, arrested or convicted of a felony or misdemeanor in any state? ○ Yes ◉ No

3. Since your last renewal or recent licensure have you been the subject of a board citation or an administrative action whe her completed or pending in any state? ◉ Yes ○ No

Cited by California Board of Pharmacy for unlicensed activity, insurance fraud, unprofessional conduct, obstruction of prescriptions. Settled case with probation

Document Name	Document Type	Date	Link	Action
Signed s ipulation La (1)	Legal - Question 3	10/02/2023	Document Details	

Document Name : Document Type : Legal - Ques ion 3

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select Date : 05/17/2023

Case # : 7019

4. Since your last renewal or recent licensure have you had your license subjected to any discipline for violation of pharmacy or drug laws in any state? ◉ Yes ○ No

California pharmacist license currently on probation

Document Name	Document Type	Date	Link	Action
stipulations	Legal - Question 4	10/02/2023	Document Details	

Document Name : Document Type : Legal - Ques ion 4

Document : Drop file here to upload or click here to browse and select file(s) to upload.

Only PDF files are allowed

Click here to complete Upload Cancel

Board Administrative Action :

State : Select Date : 05/17/2023

Case # : 7019

Criminal Action :

State : Select Date : MM/DD/YYYY

Case # :

County : Court :

CE Hours

Active ☑ By checking his box you certify you have completed ALL required CE Hours due for the 2021/2023 Renewal period. (Dated from Nov. 1, 2021 – Oct. 31, 2023; 1.25hrs per mo). The exemp ion period is 2yrs after graduation only

Acknowledgement and Declaration

I understand that it is a violation of Nevada law to falsify this application, and sanc ions may be imposed for fraud or misrepresentation. I affirm that I have read this applica ion and the statements made are true and correct. I understand and will comply with the guidelines of the Centers for Disease Control and Prevention concerning he preven ion of transmission of infec ious agents through safe injec ion prac ices. I understand that NRS 432B.220 requires that if, in my professional capacity, I know or have reason to believe that a child has been abused or neglected, I am mandated to report he abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency.

Signature : Tony La

Date Of Application : 10/02/2023

Please type only the First and Last Name that are listed at the top of the page.

Fee Detail(s)

The fees for license renewal are NON REFUNDABLE. Please ensure the accuracy of your information.

Description	Fee Type	Fee
Renewal Period from 11/1/2023 to 10/31/2025	License Renewal Fee	$200.00
	Convenience Fee	$10.00
	Late Fee	$0 00
	Total :	**$210.00**

Fee and Payment

Payment Me hod : Credit / Debit Card

Application Fees : 200

Reinstatement Fee : 0

Transac ion Fee : 10

Late Fees : 0

Reference Number : 120037707883

InvoiceDate : 10/02/2023

Paid

Pay & Submit

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
DIONNE MOCHON
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Facsimile: (619) 645-2061
E-mail: Dionne.Mochon@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:**	
PREFERRED PHARMACY, INC.; **SCOTT LEROY MONTGOMERY, CEO** **3303 Harbor Blvd., Ste. H7** **Costa Mesa, CA 92626.** **Original Permit No. PHY 54453** **and** **TONY HIEU LA** **[redacted] Abrazo Aisle** **Irvine, CA 92614** **Registered Pharmacist License No. RPH 73904** **and** **MICHAEL JEAN OLIVIE AGBASSI** **[redacted] Alamo Way** **Oceanside, CA 92057** **Registered Pharmacist License No. RPH 80700** Respondents.	Case No. 7019 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 1, 2016, the Board issued Original Permit Number PHY 54453 to Preferred Pharmacy, Inc. (Respondent Pharmacy), Scott Leroy Montgomery, CEO (Respondent Montgomery). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2023, unless renewed.

3. On or about November 3, 2015, the Board issued Registered Pharmacist License Number RPH 73904 to Tony Hieu La (Respondent La). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2023, unless renewed.

4. On or about July 31, 2019, the Board issued Registered Pharmacist License Number RPH 80700 to Michael Jean Olivie Agbassi (Respondent Agbassi). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2022, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding on year.

(4) Revoking his or her license.

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(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall

be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

9. Section 733 of the Code states:

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019 , or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

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10. Section 810 of the Code states:

…

(b) It shall constitute cause for revocation or suspension of a license or certificate for a health care professional to engage in any conduct prohibited under Section 1871.4 of the Insurance Code or Section 549 or 550 of the Penal Code.

11. Section 4040 of the Code states:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51 , 2836.1 , 3502.1 , or 3640.5 , respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1 , 4052.2 , or 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51 , 2836.1, 3502.1 , or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1 , 4052.2 , or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code , the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code , Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription

order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

12. Section 4059.5 of the Code states:

. . .

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

. . .

13. Section 4110 of the Code states:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

. . .

14. Section 4116 of the Code states:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

. . .

15. Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

16. Section 4169 of the Code states:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code Section 4301 of the Code states:

17. Section 4301 of the Code states:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

…

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board. …

18. Section 4330 of the Code states:

…

(b) Any nonpharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist in charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

…

REGULATORY PROVISIONS

19. California Code of Regulations, title 16, section 1709.1 states:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

. . .

20. California Code of Regulations, title 16, section 1714 states:

. ..

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

. . .

21. California Code of Regulations, title 16, section 1764 states:

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the

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CODE OF FEDERAL REGULATIONS

22. Title 42, Code of Federal Regulations, (CFR) section 424.57 states:

. . .

c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

. ..

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

PENAL CODE SECTIONS

23. California Penal Code section 550 states:

. . .

(a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:

. . .

(6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.

(7) Knowingly submit a claim for a health care benefit that was not used by, or on behalf of, the claimant.

. . .

CALIFORNIA CIVIL CODE SECTION

24. California Civil Code section 56.10, subdivision (a) states:

(a) A provider of health care, health care service plan, or contractor shall not disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

HEALTH AND SAFETY CODE

25. California Health and Safety Code section 111255 states:

> Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

26. California Health and Safety Code section 111295 states:

> It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

COST RECOVERY

27. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTUAL ALLEGATIONS

28. Respondent Pharmacy is a pharmacy located in Costa Mesa, California. Respondent Pharmacy primarily dispenses diabetic test strips, test meters, lancets and lancing devices, and topical creams. The Board received multiple complaints alleging Preferred Pharmacy cold-called patients in an attempt to fill prescriptions, and/or filled patient prescriptions, without authorization. Board investigations confirmed that Respondent Pharmacy cold-called patients, test-billed prescriptions, filled prescriptions without patient knowledge, and utilized an unlicensed call center to solicit potential patients to fill prescriptions.

29. Respondent La was the Pharmacist in Charge (PIC) of Respondent Pharmacy from February 1, 2017 to October 7, 2019.

30. Respondent Agbassi was the PIC of Respondent Pharmacy since October 3, 2019 until present.

31. Respondent Montgomery owns and operates a variety of businesses and pharmacies including Respondent Pharmacy, located at 2202 Harbor Blvd., Suite D, Costa Mesa, California. Respondent Montgomery is not a licensed pharmacist. RXMSO is an entity associated with

Respondent Montgomery and is located in the same building complex as Respondent Pharmacy. The Board received information that RXMSO had call centers located in California, Florida, and the Philippines. RXMSO hired affiliates that obtained patient information and sold the information to RXMSO.

COMPLAINTS TO THE BOARD

32. On or around April 4, 2018, the Board received a complaint from Pharmacist MK on behalf of a homeless patient. The patient required daily insulin and any delay in the ability to test her blood sugar could result in hospitalization. The patient learned that she could not refill her prescription for diabetic test strips through her insurance because Respondent Pharmacy previously completed and billed her insurance for the prescription test strips. The patient did not request nor receive diabetic test strips from Respondent Pharmacy and had no knowledge that the prescription was placed on her behalf. Pharmacist MK researched Respondent Pharmacy's location and determined that Respondent Pharmacy was approximately 150 miles away from the patient. Pharmacist MK called Respondent Pharmacy and was informed that Respondent Pharmacy received signature confirmation for delivery. Pharmacist MK believed that this signature could not be the patient's signature as the patient was homeless.

33. On or about September 21, 2018, the Board received an anonymous complaint alleging that a patient received a telephone call from Respondent Pharmacy. The anonymous complainant stated that the caller asked the patient to describe their pain and to provide the name of the patient's care provider so that Respondent Pharmacy could call the provider and initiate prescriptions. The patient did not know how Respondent Pharmacy received the patient's information and did not provide the requested information.

34. On or about April 17, 2020, the Board received a complaint from a former employee of RXMSO. The employee, identified as YM, believed Respondent Montgomery operated RXMSO. YM confirmed RXMSO worked with approximately seven pharmacies including Respondent Pharmacy. YM stated that Respondent Pharmacy held patient information without patient authorization. YM alleged that RXMSO employed call center agents in the Philippines, Florida, and California. None of the agents was a licensed pharmacist or pharmacy technician.

YM stated that the call centers initiated contact with prospective patients and identified themselves as "with the Health Care Department." The agent offered prospective patients such things as cookbooks or coupons for free meals to obtain patient information, including the patient's full name, date of birth, treating physician information, and last four numbers of the patient's social security number.

35. On or around September 9, 2020, the Board received an online complaint from MI, a nurse practitioner for Sutter Health. MI stated that he received a prescription request for a Medicare patient, TW, from Respondent Pharmacy. MI indicated that the patient had never been to, nor requested services from, Respondent Pharmacy.

BOARD INVESTIGATIONS

36. Based on the complaints, the Board conducted investigations and inspections of Respondent Pharmacy.

37. On or around March 6, 2019, Board Inspectors BM and CW conducted an inspection of Respondent Pharmacy located at 3303 Harbor Blvd., Suite H7, Costa Mesa, California. Respondent La assisted in the inspection. The pharmacy stocked UPS boxes and UPS label sleeves. The pharmacy's stock was comprised mostly of topical creams and diabetic products. The pharmacy Daily Fill Log appeared to be mostly diabetes supplies, including over the counter alcohol pads, lancets, meters, and strips. Inspector BM noted that one computer monitor had a screen that stated, "Allow Remote Control" and "Control Remote Computer." Respondent La confirmed that Respondent Pharmacy held an Arizona non-resident pharmacy license. Board Inspector BM viewed an expired Nevada Pharmacy license on the wall.

38. During the inspection, Board Inspectors BM and CW issued corrections for the following violations:

a.) California Code of Regulations 1707.5(d), for the pharmacy not having interpretive services;

b.) California Code of Regulations 1714(c), for the pharmacy not having a sink with hot water;

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c.) California Code of Regulations 1715.65(c), for the pharmacy not having completed an inventory reconciliation of Schedule II controlled substances; and

d.) Business and Professions Code 4070(a), for e-fax prescriptions not being reduced to hard copy form and maintained.

39. As part of the inspection, Inspector BM interviewed Respondent La who stated the following:

a.) Respondent Montgomery knew more about the pharmacy procedures than Respondent La.

b.) Respondent La did not know about the marketing procedures and did not know if Respondent Pharmacy cold-called patients.

c.) Respondent Pharmacy received prescriptions via e-script or e-fax and automatically placed patient prescriptions on auto refill.

d.) E-scripts came directly from the prescribers via a Faxage server.[1] Inspector BM could not locate printed E-faxed prescriptions.

e.) Respondent Pharmacy used a delivery driver and did not mail prescriptions. Approximately half of Respondent's patients walked into the premises to fill prescriptions and prescriptions were set for auto refills. Respondent La did not know exactly how the prescriptions were delivered to locations several hours from Respondent Pharmacy's location.

40. Inspector BM asked Respondent La to log into Respondent Pharmacy's computer system. Respondent La could not log in to the fax server and called Respondent Montgomery. Once Respondent La gained access, Board Inspector BM reviewed prescriptions received by fax. The system organized prescriptions by the prescriber fax number and date/time. While reviewing Respondent Pharmacy's prescriptions, Board Inspector BM found:

a.) Respondent Pharmacy stocked preprinted prescriptions that appeared to be created by Respondent Pharmacy or a marketing company and included a fine print disclaimer

[1] A faxage server is a third-party faxing vendor fax that collects the prescriptions from doctors which then gets entered into a computer system, instead of the prescription being sent directly to the pharmacy.

that the prescriber's signature authorized the pharmacy to "substitute as necessary any comparable cream formulation, patch, gel, or kit."

b.) Inspector BM pulled two examples of preprinted prescriptions. One prescription was for Patient RD for lidocaine 5% ointment with three refills, and the other prescription was for CP for calcipotriene 0.005% cream with 5 refills. The prescriptions appeared to be created by Respondent Pharmacy or a marketing group and requested the prescription be faxed back to an unidentified toll free number. The prescriptions contained a disclaimer in fine print at the bottom that indicated that the prescriber's signature authorized the pharmacy to "substitute as necessary any comparable cream formulation, patch, gel, or kit."

c.) A review of Patient TW's file included a pre-printed fax that appeared to have been created by Respondent Pharmacy, although the prescription did not include the pharmacy name. The prescription included preprinted information such as the patient name, address, date of birth, and the prescriber name, address, phone number, fax number, and National Provider Identifier (NPI). The prescription advised the prescriber to fax the prescription back to an unidentified toll free number. The prescription contained generic prescriptions of diabetic test strips, lancets, alcohol prep pads, lancet device, glucose meter, control solution, and syringes, all with a 90-day quantity or single device listed in the quantity. The prescription included a section for refills, but three refills appeared to be already electronically circled on the prescription. The prescription was signed and dated June 24, 2017, however a signature log for the patient was not retrievable during inspection. Patient TW resided in Bakersfield. Respondent La stated that distant deliveries used a different system and that he did not have access to that system.

d.) Respondent La could not pull additional sample signatures for delivery when asked to do so by Board Inspector BM.

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Marketing Relationship with RXMSO

41. RXMSO is an entity associated with Respondent Montgomery and is located in the same building complex as Respondent Pharmacy. RXMSO includes a call center that contacted prescribers and patients to obtain prescriptions, demographics, and insurance information and access pharmacy systems to upload patient and prescription information on behalf of Respondent Pharmacy. There was no pharmacist overseeing RXMSO.

42. RXMSO company training documents included a coverage check process, a script for calling patients, RXMSO training, and a store contact list. The training document described the "Doc Chase" process, where after the pharmacy "approves a prescription," the RXMSO employee would attempt to obtain a prescription from the provider. Training documents included a prepared script for the employee to use when calling the prescriber. The training material instructed the employee to attempt to obtain a prescription by contacting the prescriber twice a day for approximately seven days. The documents described another process, the "Reverse Que," in which the agent would reverse or "credit return" billed prescriptions and then rebill them. The materials used by RXMSO were provided to employees of Respondent Pharmacy.

43. Beginning with the COVID-19 pandemic, call center employees worked from home. RXMSO affiliates cold-called patients and identified themselves as from the "health department." Once the affiliates obtained patient information, "coverage checkers" verified prescription profitability. If patients requested refills of prescriptions deemed "not profitable" to the pharmacy, the pharmacy would inform the patient "their insurance was telling the pharmacy to have the patient use a local community pharmacy" even though the pharmacy had not spoken with the patient's insurance company. If the claim was approved, the patient would move to the "doc chase" department. Members of the "doc chase" department would call prescribers and inform the prescriber that they previously spoke with the patient, even though the "doc chase" employee had not spoken with the patient. The "doc chase" employees received commissions based on how many prescriptions they obtained.

44. On or around August 19, 2020, Board Inspectors traveled to Respondent Pharmacy to tour the call center and to conduct a follow up interview of Respondent Agbassi. Respondent

Agbassi indicated that the call center ceased onsite operations and that he did not have access to the call center space. Respondent Agbassi stated that the company recently downsized and had only one call center employee. Respondent Agbassi believed Respondent Montgomery previously had access to the call center and oversaw the operations on occasion.

45. During the Board investigator's interview with Respondent Agbassi, Respondent Montgomery arrived. Inspector BM interviewed Respondent Montgomery. Respondent Montgomery admitted that Respondent Pharmacy bought patient leads from a marketer, or Management Services Organization in this case, RXMSO. The call center employed approximately five employees who worked from home due to COVID-19 shelter-in-place orders.

Test Billing and Solicitation of Prescriptions

46. A review of Respondent Pharmacy's data indicated as follows:

a.) The data was comprised of approximately 50,000 prescriptions.

b.) Respondent Pharmacy marked approximately 31,680 prescriptions as "completed."

c.) Respondent Pharmacy reversed billing in approximately 18,318 prescriptions, resulting in approximately 37% of prescriptions being cancelled.

d.) Respondent Pharmacy data reflected that there were approximately 5,333 patients who only had prescriptions that were in cancelled status, indicating that Respondent Pharmacy typed and attempted to process prescriptions for 5,333 patients for whom Respondent Pharmacy had never filled prescriptions. This is a red flag that indicated Respondent test billed prescriptions, that is, Respondent Pharmacy submitted fraudulent insurance claims to determine if the prescription would result in a profit for the pharmacy.

e.) Data from February 1, 2017, through October 7, 2019, indicated that Respondent La verified approximately 30,323 prescriptions as PIC, while Respondent Agbassi verified approximately 976 prescriptions as PIC. Over 18,000 prescriptions did not list a pharmacist in the verified by column, indicating no pharmacist reviewed or dispensed the prescription.

f.) Although Respondent La alleged that Respondent Pharmacy only utilized a delivery driver for delivering prescriptions, Respondent Pharmacy held prescriptions for patients from 821 separate California cities. Respondent Pharmacy only completed approximately 30 prescriptions in Costa Mesa, where Respondent Pharmacy was located, representing 0.11% of Respondent's prescriptions. The top cities where Respondent Pharmacy completed prescriptions are as follows:

Patient City	Distance from Costa Mesa (approximate miles)	Count of Rx Number	Percentage of Total Rx's
Sacramento	427	1894	5.98%
Los Angeles	41	1591	5.02%
Fresno	261	1294	4.08%
San Diego	87	850	2.68%
Bakersfield	154	814	2.57%
Long Beach	28	646	2.04%
Modesto	354	592	1.87%
Lancaster	113	549	1.73%
San Bernardino	56	424	1.34%
Victorville	88	413	1.30%

47. Dr. LM appeared in approximately 2,489 prescriptions. Of these prescriptions, approximately 2,445 prescriptions were cancelled and only 44 were completed. Dr. LM's address of record was approximately fifty miles from the pharmacy. The patients listed as Dr. LM's "patients" resided throughout the state and not near Respondent Pharmacy nor Dr. LM's office. Dr. LM's office confirmed via questionnaire that out of the approximately 2,445 prescriptions provided by Inspector BM, only 19 of those patients ~~(27 total prescriptions)~~ were under Dr. LM's care. The remaining approximately 2,171 separate patients had prescriptions created by Preferred Pharmacy that were not patients of Dr. LM. Thus, approximately 2,426 separate prescriptions were created by Preferred Pharmacy using Dr. LM's name. Dr. LM stated that he had not authorized the pharmacy to create prescriptions for the patients that were not his patients. Dr. LM did note that he had sent some prescriptions to the pharmacy for the 19 patients under his care but stated that Respondent Pharmacy test billed approximately 2,426 prescriptions under Dr. LM's name without his authorization.

48. Dr. DS confirmed that Respondent Pharmacy test billed 56 prescriptions that were not authorized. Dr. DS stated that he was not familiar with Respondent Pharmacy, did not prescribe these types of prescriptions (test strips, lancets, alcohol pads), had not authorized Respondent Pharmacy to test bill prescriptions under his name, and that the patients on the list of prescriptions provided were not his patients. Dr. DS's office confirmed 56 prescriptions had not been authorized by the prescriber.

49. Dr. DD confirmed that he did not authorize approximately 19 prescriptions that were test billed by Respondent Pharmacy. Dr. DD retired on January 25, 2019, and he confirmed that he did not write any prescriptions after that date. Additionally, Dr. DD stated that he was not familiar with Respondent Pharmacy, was located more than 500 miles from Respondent Pharmacy, did not perform telemedicine, and only saw patients in person. Thus, it was unlikely that he authorized any prescriptions for patients located outside of Paradise, California.

50. An employee of Respondent Pharmacy and RXMSO confirmed that Respondent Pharmacy test billed prescriptions to ensure that the prescriptions were profitable. The employee explained that if Respondent Pharmacy could make $35.00 from the patient's prescription, then it would pursue obtaining the prescription. The employee confirmed that if the patient wanted a refill or a prescription but the profit was less than $35.00, or if the patient had a high copay, Respondent Pharmacy would lie to the patient and tell the patient that their insurance informed Respondent Pharmacy to have the patient use a local community pharmacy instead.

51. Inspector BM contacted patients that received prescriptions from Respondent Pharmacy. Responding patients indicated that Respondent Pharmacy billed their insurance in some instances, that they received cold calls in an attempt to obtain authorization to bill and obtain prescriptions for the patient, that they had not contacted Respondent Pharmacy directly to fill prescriptions. By way of example, the following patients stated the following:

a.) Patient DJ stated that she received supplies from Respondent Pharmacy that she had not requested. She had not been to the pharmacy and did not know how Respondent Pharmacy obtained her information. Patient DJ confirmed that she was cold-called by

Respondent Pharmacy. She further confirmed that she did not authorize Respondent Pharmacy to bill her insurance.

b.) Patient RP indicated that she received prescriptions from Respondent Pharmacy but that she had not been to, did not provide a prescription to, and did not know how Respondent Pharmacy obtained her contact information. Patient RP confirmed that Respondent Pharmacy cold-called her.

c.) Patient JM stated that he had not received or requested prescriptions from Respondent Pharmacy. Patient JM stated that he did not authorize Respondent Pharmacy to bill his insurance. Patient JM's prescription was listed as "cancelled" in the computer system.

d) Respondent Pharmacy declined to fill a prescription for S.O. after her insurance changed and the pharmacy noted "New Insurance no longer meets margin, will D/C Patient In Pioneers" according to a screenshot provided.

52. On or around November 21, 2019, Respondent La participated in a conference call with Board Inspectors and confirmed that Respondent Pharmacy used "RXMSO" employees known as "chasers." Contrary to what Respondent La previously stated, Respondent Pharmacy mailed about 90% of the prescriptions. Patients called and asked why they received prescriptions from Respondent Pharmacy. "RXMSO" staff that called these patients were different from the "chasers." Respondent Pharmacy sometimes received returns from patients. Those prescriptions were returned for destruction and reversed from billing. Respondent La explained the prescription would be filled typically by him, given to the clerk who would label it for shipping, and the driver would collect the boxes for delivery via "DCS."

Adulterated Prescriptions

53. Respondent Pharmacy accepted prescriptions returned by patients. If a patient returned a prescription, Respondent Agbassi would reverse the insurance charge and examine the product. If the product appeared intact and still sealed, Respondents would re-dispense the product despite having no knowledge of the conditions in which the products were kept.

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Lack of Pharmacy Security

54. On or around September 9, 2019, Inspector BM conducted another inspection of Respondent Pharmacy. Upon entering the pharmacy, Inspector BM found that two clerks and pharmacy technicians EL and YT were present in the pharmacy with computers running and patient profiles visible on one screen and without a pharmacist present. Pharmacy technicians possessed keys to enter the pharmacy. Although the pharmacy maintained a small stock of dangerous drugs in the front locked room, test strips, pharmacy computers, and patient prescriptions were located in the main pharmacy area.

FIRST CAUSE FOR DISCIPLINE

(Interference with Pharmacist in Charge

Against Respondent Pharmacy and Respondent Montgomery)

55. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301 subdivision (o), for violating California Code of Regulations, title 16, section 1709.1, subdivision (b), and Code section 4330, subdivision (b), in that Respondent Pharmacy and Respondent Montgomery utilized an unlicensed, offsite call center to contact patients and prescribers; maintained fax servers to receive prescriptions that the Pharmacist-in-Charge could neither access nor locate; and, used delivery systems that the Pharmacist-in-Charge did not have knowledge of, access to, nor control over, as described above in paragraphs 28 through 54 which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Unlicensed Activity Against All Respondents)

56. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), for violating Code section 4110, subdivision (a), in that Respondents utilized an unlicensed entity, RXMSO, to run a call center to contact prescribers and patients to obtain prescriptions and access pharmacy systems to upload patient and prescription information. This location was not supervised by a pharmacist and was not licensed by the Board, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

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THIRD CAUSE FOR DISCIPLINE

(Unauthorized Disclosure of Prescription Information

Against Respondent Pharmacy and Respondent Montgomery)

57. Respondents are subject to disciplinary action under Code sections 4301 subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1764, and California Civil Code section 56.10, subdivision (a), in that Respondent Pharmacy and Respondent Montgomery ran an unlicensed call center that contacted prescribers and patients to obtain prescriptions, demographics, and insurance information and accessed pharmacy systems to upload patient and prescription information. The call center was not supervised by a pharmacist and was manned by unlicensed staff, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Insurance Fraud Against All Respondents)

58. Respondents are subject to disciplinary action under Code sections 4301 subdivisions (j) and (o), for violating Code section 810, subdivision (b) and Penal Code section 550 subdivision (a)(6) and (7), in that Respondent Pharmacy knowingly made or caused to be made any false or fraudulent claim for payment of a health care benefit and knowingly submitted a claim for a health care benefit that was not used by, or on behalf of, the claimant. Specifically, and as more fully set forth in paragraphs 46 through 52 above, between February 1, 2017, and November 7, 2019, Respondents cancelled 18,318 prescriptions in the computer system and had approximately 5,333 patients who only had prescriptions that were in the cancelled status (the pharmacy entered a prescription for them but never dispensed drugs or products). These 18,318 claims represented approximately 37% of Respondent Pharmacy's typed prescriptions and suggests that Respondent Pharmacy was test-billing and soliciting prescriptions it knew it would not be dispensing. Additionally, patients confirmed that Respondent Pharmacy cold-called patients and billed their insurance either without the patient's authorization and/or without the patient requesting prescriptions be filled by Respondent Pharmacy.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct Against All Respondents)

59. Respondent Pharmacy is subject to disciplinary action under Code sections 4301 subdivisions (f), (g) and (o) in that Respondent Pharmacy test-billed insurance claims the patient did not receive, billed patient's insurance without authorization, ran an unlicensed call center that accessed patient prescription information, cold-called patients, and lied about cold calling patients, as described above in paragraphs 44 through 52, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Subverting an Investigation

Against Respondent Pharmacy, Respondent Montgomery and Respondent La)

60. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301, subdivision (q), in that Respondent Pharmacy, Respondent Montgomery and Respondent La each signed a written statement denying that patients were cold-called, stating that pharmacy personnel delivered prescriptions despite prescriptions being shipped hundreds of miles away, and denying that marketers had access to pharmacy records despite marketers calling patients and prescribers regarding their prescriptions, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by a Corporation

Against Respondent Pharmacy and Respondent Montgomery)

61. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301, subdivision (o), in conjunction with Code section 4156 in that Respondent Pharmacy and Respondent Montgomery test-billed insurance claims for prescriptions the patients did not receive, billed patients' insurance without authorization, ran an unlicensed call center that accessed patient prescription information, cold-called patients, and lied about cold calling patients, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Obstruction of Prescriptions Against All Respondents)

62. Respondents are subject to disciplinary action under Code sections 4301, subdivisions (f) and (o), and Code section 733, subdivision (a) and (b), in that Respondents' policies and procedures confirmed the pharmacy would not ship a patient their prescription if the prescription did not meet a set profit margin, including if the patient was receiving a refill for a prescription previously filled by the pharmacy. In addition, Respondents declined to fill prescriptions for Patient SO after her insurance changed and her file noted "new insurance no longer meets margin," as described above in paragraphs 28 through 54, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Adulterated Drugs Against all Respondent Pharmacy and Respondent Agbassi)

63. Respondent Pharmacy, Respondent Montgomery and Respondent Agbassi are subject to disciplinary action under Code sections 4301, subdivision (j), Code section 4169, subdivision (a)(1) and (2), and Health and Safety Code sections 111255 and 111295 in that Respondents sold, delivered, held, or offered for sale an adulterated drug, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Lack of Pharmacy Security

Against Respondent Pharmacy and Respondent Agbassi)

64. Respondent Pharmacy, Respondent Montgomery and Respondent Agbassi are subject to disciplinary action under Code sections 4301 subdivision (j), Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that non-pharmacist personnel had a key to the pharmacy premises, which allowed access to pharmacy computer systems and records an hour prior to the arrival of the pharmacist, as described above in paragraph 54, which is incorporated herein by reference.

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OTHER MATTERS

65. Pursuant to Section 4307, if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

66. Pursuant to Section 4307, if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, and Respondent Agbassi, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 54453 was revoked, suspended, or placed on probation, Respondent Agbassi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

67. Pursuant to Section 4307, if Pharmacy Permit Number PHY54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, and Respondent Montgomery, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 54453 was revoked, suspended, or placed on probation, Respondent Montgomery shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

68. Pursuant to Section 4307, if Pharmacist License Number RPH 73904 issued to Tony Hieu La is suspended or revoked, Respondent La shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

69. Pursuant to Section 4307, if Pharmacist License Number RPH 80700 issued to Michael Jean Olivie Agbassi is suspended or revoked, Respondent Agbassi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number PHY 54453, issued to Preferred Pharmacy, Inc.; Scott Leroy Montgomery, CEO;

2. Revoking or suspending Registered Pharmacist License Number RPH 73904, issued to Tony Hieu La;

3. Revoking or suspending Registered Pharmacist License Number RPH 80700, issued to Michael Jean Olivie Agbassi;

4. Ordering Tony Hieu La, Michael Jean Olivier Agbassi and Scott Leroy Montgomery to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Prohibiting Preferred Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54453 is placed on probation or until Pharmacy Permit Number PHY 54453 is reinstated if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy is revoked;

6. Prohibiting Scott Montgomery from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54453 is placed on probation or until Pharmacy Permit Number PHY 54453 is reinstated if it is revoked;

7. Prohibiting Tony Hieu La from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 73904 is placed on probation or until Registered Pharmacist License Number RPH 73904 is reinstated if it is revoked; and,

8. Prohibiting Michael Jean Olivie Agbassi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 80700 is placed on probation or until Registered Pharmacist License Number RPH 80700 is reinstated if it is revoked; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 8/31/2022

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 1, 2023

Tony La
[redacted]Abrazo Aisle
Irvine, CA 92614

RE: Administrative Case 7019

Dear Tony La:

This letter is regarding the above referenced administrative case. I am the probation analyst that has been assigned to your case. I am in the process of setting up your file and planning your upcoming office conference.

Please email BOPProbation@dca.ca.gov with your name, current email address and contact telephone number. You will be notified by email and/or mail of your set office conference date and time.

If you have any questions, please feel free to contact me at Autumn.Ammann@dca.ca.gov.

Sincerely,

Autumn Ammann
Probation Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
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www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

May 1, 2023

CERTIFIED & FIRST-CLASS

Tony La
[redacted] Abrazo Aisle
Irvine, CA 92614

RE: **AC 7019 – Office Conference**

Dear Tony La,

In accordance with the terms and conditions of your probation, you are hereby required to report **IN PERSON** at an office conference. The office conference will be held via Microsoft Teams video conference on **May 15, 2023** at **1:30pm.**

This conference has been scheduled to introduce you to your probation team that will be assisting you through this probationary period, to advise you of their functions and responsibilities, and to review and clarify the terms of probation.

Instructions for joining the Microsoft Teams Video Conference:

- Please use a laptop or desktop computer with camera access. If you do not have access to a desktop computer with a camera, please notify your probation analyst prior to your scheduled conference.
- At your scheduled conference time, select "Click here to join the meeting" (link found below these instructions).
- Enter the "Meeting ID" and "Passcode".
- When prompted, select "Continue on this Browser/Internet/Web". *You do not need to download Microsoft Teams.*
- Ensure video and microphone/audio are enabled.
- Enter your first and last name, click "Join now", and wait to be admitted to the meeting.
- If you experience technical issues, please use the "call in for audio" instructions listed below for assistance.

Microsoft Teams meeting

Join on your computer or mobile app
Click here to join the meeting
or go to https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting?rtc=1
Meeting ID: **253 523 169 323**
Meeting Passcode: **377P4i (case sensitive)**

At least 48 hours prior to your scheduled conference email BOPprobation@dca.ca.gov the following:

- Confirmation that you will be in attendance.
- Best contact information for the duration of probation (email, phone number, work phone number).

Please ensure the following for your scheduled video conference:

- Locate a quiet, distraction-free location for the duration of the conference.
- Ensure your electronic device is fully charged and have charging capabilities, if needed.
- Have the following documents in front of you for the duration of the conference, please review prior:
  - Your decision and order.
  - This letter with the ancillary forms and guidelines that were attached. These documents will be reviewed during the conference and additional directions will be provided.

Pursuant to the terms and conditions of your probation, you shall appear for interviews with the board upon request at various intervals. Failure to appear for a scheduled interview without prior notification to the board shall be considered a violation of probation.

Call in for audio (only if needed day of office conference)
Dial (916) 461-9649
Enter in conference ID: **971 495 437**
Press #

If you have any questions, you may contact your probation analyst at BOPProbation@dca.ca.gov.

Sincerely,

Autumn Ammann
Probation Analyst

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Tony La, RPH 73904

I am over 18 years of age and not a party to the within entitled cause; my business address is 2720 Gateway Oaks Dr. Suite 100, Sacramento, CA 95833. I served the document below:

LETTER: NOTICE TO APPEAR

on each of the following, by placing same in an envelope addressed as follows:

NAME	CERTIFIED MAIL NO.
Tony La [redacted] Abrazo Aisle Irvine, CA 92614	7017 0530 0000 3305 4648

And that said envelope was sealed and deposited in a designated location for collection by staff and for mailing by certified mail with postage fully prepaid thereon and return receipt service by the U.S. Postal Service in accordance with ordinary business practices.

I declare under penalty of perjury that the forgoing is true and correct. Executed on May 1, 2023, in Sacramento, California.

DECLARANT
Connor Shaughnessy
Probation Office Technician

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Quarterly Report

UPDATED (6/9/2021)

The terms and conditions of your probation require that you report quarterly to the board during the period of probation. It is your responsibility to ensure that the board receives your reports by the **10th of January, April, July, and October** of each year of probation.

You are required to include the following information in each report in full detail:
(if not applicable please note N/A)

1. Your Personal Information:
    - Name
    - License number
    - Case number
    - Current home address
    - Best contact number
    - Email

2. Your Work Information:
    - Pharmacy name
    - Pharmacy license number
    - Pharmacy license address
    - Best contact number for your employer
    - Name of pharmacist-in-charge
    - Name of your supervisor (if not the PIC)

3. Information on your employment:
    - Number of hours worked by month for the quarter
    - Work schedule for the next quarter
    - General description of your duties and responsibilities

**Please note, unpaid (volunteer) positions may not be used as hours worked to satisfy community service requirements.*

4. If you are not working in the field of pharmacy:
    - Employer Name
    - Employer Address
    - Best contact number of your employer
    - General description of your duties
    - Hours worked per month
    - Work schedule for the next quarter
    - Your plans in obtaining employment in the field of pharmacy

5. Describe how you remain current with laws and regulations governing the practice of pharmacy. Provide a list of titles of pharmaceutical literature you have read and a list of continuing education courses you have completed.

**Please note, to receive credit for remedial education you must attach the corresponding approval letter to the copies of your certificates of completion or your official CPE transcripts and email to BOPprobation@dca.ca.gov (subject line should include your first name, last name, license number and "RE completion").*

6. List other professional activities.

7. Do you have any questions and/or problems adhering to pharmacy laws and regulations?

8. **Include the following statement on each quarterly report. All reports must be signed and dated and must include the following statement:**

    I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Email report as a **PDF attachment** to BOPprobation@dca.ca.gov

- Subject line must include first name, last name, license number and "quarterly report"
    - ex. Jane Doe RPH 55555 quarterly report
- Only pdf attachments will be accepted. All other formats will not be accepted, and your report will be considered as missing.

If you have any questions, please contact your Probation Analyst at BOPProbation@dca.ca.gov.

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VERIFICATION OF EMPLOYMENT

The licensee named below has been placed on probation with the Board of Pharmacy. Conditions of probation require that they notify you, the Pharmacist in Charge and owner/employer, of their probationary status by submitting a copy of the Board's decision to you.

Probationer's Information:

Name: _____ License #: _____

Probation period: From: _____ To: _____

This section below is to be completed by the Pharmacist in Charge and Owner/Employer

Probationer's work information:

Position title: _____ Date hired: _____

Full-time: _____ Part-time: _____

Hours per shift: _____ Approximate hours per month: _____

Physical location where probationer is working:

Pharmacy name: _____ Pharmacy license #: _____

Street address: _____

City: _____ State: _____ Zip code: _____

CONTINUED ON PAGE 2

Pharmacist-In-Charge's information and acknowledgment:

Your signature verifies that you have read the board's decision that places this licensee on probation. You agree to ensure that the probationer's work environment is according to the terms and conditions of probation.

Name: _____ License #: _____

Email: _____ Telephone #: (_____) _____

Signature: _____ Date: _____

Owner/Corporate Representative's acknowledgment:

Your signature verifies that you have read the board's decision that places this licensee on probation. You agree to ensure that the probationer's work environment is according to the terms and conditions of probation.

Print name: _____

Signature: _____ Date: _____

This section below is to be completed by the Probationer

I authorize the board or its designee's to communicate with my employer and supervisor(s), and authorize my employer or supervisor(s) to communicate with the board or its designee's concerning my work status, performance and monitoring.

I hereby certify under penalty of perjury under the laws of the state of California to the truth and accuracy of all statements, answers, and representations made in this document.

Print name: _____

Signature: _____ Date: _____

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NOTIFICATION OF EMPLOYMENT TERMINATION

Licensees on probation are required to provide written notification to the Board of change in employment status within 10 days of the cessation of the practice of pharmacy.. Please complete this form and return it to the attention "Probation Monitor" at the Board office within 10 days of receipt.

Licensee Information

Licensee Name: _____ License #: _____

Mailing Address: _____

_____

_____

Last Place of Employment (with Pharmacy License required)

Name of Pharmacy: _____ License #: _____

Street Address: _____

City: _____ Zip Code: _____

*First Date of Employment: _____ Typical # Hours per Week: _____

*Last Date of Employment: _____

*Last Day Worked: _____

□ Check box if you have never worked in the practice of pharmacy.

I represent to the Board that all of the statements provided by me on this form are true and correct.

_____ _____
Signature Date

* List dates of last employment location where licensure was required regardless of whether employment was during probation period.

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Ethics Course

One of the terms of your probation is completion of an ethics course approved by the Board. This letter will provide you with information about available courses. According to Title 16 California Code of Regulations, section 1773.5, the ethics course must consist of at least 22 hours of specified components. A copy of the regulation describing these required components is provided on the following page.

Professional Boundaries Inc. offers ethics courses. The Board does not operate these courses or endorse the company. You may contact Professional Boundaries Inc., at (904) 800-1237 www.professionalboundaries.com. This provider has represented to the Board that they comply with the regulations as set forth in Title 16 California Code of Regulations, section 1773.5. Before enrolling in any course for the purposes of satisfying the terms and conditions of probation, please review the regulations to ensure the course will fulfill the requirements specified in the regulation.

Once you have enrolled in the course, please submit proof of enrollment to your Probation Analyst at the above address. As a reminder, a certificate of completion must be mailed to the Board office within five days after completing the course.

1773.5 Ethics Course Required as Condition of Probation.

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:
   (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
   (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
   (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
   (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
   (5) Content. The course shall contain all of the following components:
      (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
      (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
      (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.
      (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
      (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.
      (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
   (6) Class Size. A class shall not exceed a maximum of 12 participants.
   (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
   (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
   (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

California State Board of Pharmacy

Payment Plan Request

I, _____, license number _____

request the California Board of Pharmacy to approve a payment plan for cost of investigation and prosecution incurred for AC#_____. I request to pay $_____ as indicated below.

☐ Pay amount in full by: _____

☐ Make monthly payments (due by the 10th of each month)

First payment of $ _____ to be made on _____ with the last payment of $ _____ to be made on _____.

Print Name _____

Signature _____

Date _____

Approved By: _____ Date: _____

Administrative Case: AC 7019

License #: RPH 73904

DATE: May 15, 2023 **TIME: 1:30pm**

DECLARATION

I, Tony La, declare that I have interviewed with the Board of Pharmacy representatives at the above date and time.

The terms and conditions of my probation have been fully explained to me by the Board representatives. I hereby acknowledge that I thoroughly understand these terms and conditions as set forth in the disciplinary action and that failure to comply may result in further disciplinary action.

_____

Tony La, RPH 73904

DATE: _____

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
DIONNE MOCHON
Deputy Attorney General
State Bar No. 203092
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9012
Facsimile: (619) 645-2061
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **PREFERRED PHARMACY, INC.;** **SCOTT LEROY MONTGOMERY, CEO** **3303 Harbor Blvd., Ste. H7** **Costa Mesa, CA 92626.** **Original Permit No. PHY 54453** **and** **TONY HIEU LA** **[redacted] Abrazo Aisle** **Irvine, CA 92614** **Registered Pharmacist License No. RPH 73904** **and** **MICHAEL JEAN OLIVIE AGBASSI** **[redacted] Alamo Way** **Oceanside, CA 92057** **Registered Pharmacist License No. RPH 80700** Respondents.	Case No. 7019 OAH No. 2022110412 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RESPONDENT TONY HIEU LA ONLY**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Dionne Mochon, Deputy Attorney General.

2. Tony Hieu La (Respondent) is represented in this proceeding by attorney Luis Andre P. Vizcocho, whose address is: 9090 Irvine Center Drive, Irvine, California 92618.

3. On or about July 31, 2019, the Board issued Registered Pharmacist License No. RPH 73904 to Respondent La. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in Accusation No. 7019, and will expire on July 31, 2023, unless renewed.

JURISDICTION

4. Accusation No. 7019 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on September 2, 2022. Respondent timely filed his Notice of Defense contesting the Accusation.

5. A copy of Accusation No. 7019 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7019. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right

to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. Respondent understands and agrees that the charges and allegations in Accusation No. 7019, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License.

10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and Respondent hereby gives up his right to contest those charges.

11. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Registered Pharmacist License No. RPH 73904 issued to Respondent Tony Hieu La is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions:

1. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent shall timely cooperate with the board's inspection program and with the board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

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5. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7019 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the board in writing the name, physical address, and mailing address of each of Respondent's employer(s), and the name(s) and telephone number(s) of all of Respondent's direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the board a written consent authorizing the board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the board or its designee, concerning Respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) Respondent's direct supervisor, (b) Respondent's pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of Respondent's employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7019, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent La's's responsibility to ensure that these acknowledgment(s) are timely submitted to the board. In the event of a change in the

person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7019, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the board of the decision in case number 7019, and the terms and conditions imposed thereby in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether the Respondent is an employee, independent contractor or volunteer.

7. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall further notify the board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

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8. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

9. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent shall pay to the board its costs of investigation and prosecution in the amount of $20,000.00. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

Respondent shall be permitted to pay these costs in a payment plan approved by the board or his designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

10. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Status of License**

Respondent shall, at all times while on probation, maintain an active, current Registered Pharmacist License with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Registered Pharmacist License shall be considered a violation of probation.

If Respondent's Registered Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

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12. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his license, including any indicia of licensure issued by the board, along with a request to surrender the license. The board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

13. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 100 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10)

days following the next calendar month during which Respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The board or its designee may post a notice of the extended probation period on its website.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent, and the board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided and the charges and allegations in Accusation No. 7019 shall be deemed true and correct.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

16. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll in a course in ethics, at Respondent’s expense, approved in advance by the board or its

designee that complies with Title 16 California Code of Regulations section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the board or its designee, shall be considered a violation of probation. Respondent shall be given credit for the live portion of the ethics course that was completed within twelve (12) months prior to the effective date of this Decision and Order, so long as Respondent provides sufficient documentation confirming completion of that portion of the course.

17. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Luis Andre P. Vizcocho. I understand the stipulation and the effect it will have on my Registered Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 3/15/23

TONY HIEU LA
Respondent

I have read and fully discussed with Respondent Tony Hieu La the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 03-15-2023

Luis Andre P. Vizcocho
Attorney for Respondent Tony Hieu La

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General

DIONNE MOCHON
Deputy Attorney General
Attorneys for Complainant

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I have read and fully discussed with Respondent Tony Hieu La the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

Luis Andre P. Vizcocho
Attorney for Respondent Tony Hieu La

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: March 15, 2023

Respectfully submitted,

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General

DIONNE MOCHON
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7019

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:** **PREFERRED PHARMACY, INC.;** **SCOTT LEROY MONTGOMERY, CEO** **3303 Harbor Blvd., Ste. H7** **Costa Mesa, CA 92626.** **Original Permit No. PHY 54453** **and** **TONY HIEU LA** **[redacted] Abrazo Aisle** **Irvine, CA 92614** **Registered Pharmacist License No. RPH 73904** **and** **MICHAEL JEAN OLIVIE AGBASSI** **[redacted] Alamo Way** **Oceanside, CA 92057** **Registered Pharmacist License No. RPH 80700** Respondents.	Case No. 7019 OAH No. 2022110412

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on _____.

It is so ORDERED _____

_____
FOR THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

ROB BONTA
Attorney General of California
MARICHELLE S. TAHIMIC
Supervising Deputy Attorney General
DIONNE MOCHON
Deputy Attorney General
State Bar No. 203092
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9012
Facsimile: (619) 645-2061
E-mail: Dionne.Mochon@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against**:**	
PREFERRED PHARMACY, INC.; SCOTT LEROY MONTGOMERY, CEO **3303 Harbor Blvd., Ste. H7** **Costa Mesa, CA 92626.** **Original Permit No. PHY 54453** **and** **TONY HIEU LA** **[redacted] Abrazo Aisle** **Irvine, CA 92614** **Registered Pharmacist License No. RPH 73904** **and** **MICHAEL JEAN OLIVIE AGBASSI** **[redacted] Alamo Way** **Oceanside, CA 92057** **Registered Pharmacist License No. RPH 80700** Respondents.	Case No. 7019 **ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about June 1, 2016, the Board issued Original Permit Number PHY 54453 to Preferred Pharmacy, Inc. (Respondent Pharmacy), Scott Leroy Montgomery, CEO (Respondent Montgomery). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2023, unless renewed.

3. On or about November 3, 2015, the Board issued Registered Pharmacist License Number RPH 73904 to Tony Hieu La (Respondent La). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2023, unless renewed.

4. On or about July 31, 2019, the Board issued Registered Pharmacist License Number RPH 80700 to Michael Jean Olivie Agbassi (Respondent Agbassi). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2022, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding on year.

(4) Revoking his or her license.

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(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

. . .

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, or partner," as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall

be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

9. Section 733 of the Code states:

(a) A licentiate shall not obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019 , or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

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10. Section 810 of the Code states:

…

(b) It shall constitute cause for revocation or suspension of a license or certificate for a health care professional to engage in any conduct prohibited under Section 1871.4 of the Insurance Code or Section 549 or 550 of the Penal Code.

11. Section 4040 of the Code states:

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51 , 2836.1 , 3502.1 , or 3640.5 , respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1 , 4052.2 , or 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51 , 2836.1, 3502.1 , or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1 , 4052.2 , or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code , the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code , Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription

order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

12. Section 4059.5 of the Code states:

. . .

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

. . .

13. Section 4110 of the Code states:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

. . .

14. Section 4116 of the Code states:

(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

. . .

15. Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

16. Section 4169 of the Code states:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code Section 4301 of the Code states:

17. Section 4301 of the Code states:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct includes, but is not limited to, any of the following:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

…

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board. …

18. Section 4330 of the Code states:

…

(b) Any nonpharmacist owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist in charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

…

REGULATORY PROVISIONS

19. California Code of Regulations, title 16, section 1709.1 states:

(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.

(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

. . .

20. California Code of Regulations, title 16, section 1714 states:

. ..

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

. . .

21. California Code of Regulations, title 16, section 1764 states:

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.

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CODE OF FEDERAL REGULATIONS

22. Title 42, Code of Federal Regulations, (CFR) section 424.57 states:

. . .

c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards:

. ..

(11) Must agree not to contact a beneficiary by telephone when supplying a Medicare-covered item unless one of the following applies:

(i) The individual has given written permission to the supplier to contact them by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

PENAL CODE SECTIONS

23. California Penal Code section 550 states:

. . .

(a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:

. . .

(6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.

(7) Knowingly submit a claim for a health care benefit that was not used by, or on behalf of, the claimant.

. . .

CALIFORNIA CIVIL CODE SECTION

24. California Civil Code section 56.10, subdivision (a) states:

(a) A provider of health care, health care service plan, or contractor shall not disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

HEALTH AND SAFETY CODE

25. California Health and Safety Code section 111255 states:

> Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

26. California Health and Safety Code section 111295 states:

> It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

COST RECOVERY

27. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTUAL ALLEGATIONS

28. Respondent Pharmacy is a pharmacy located in Costa Mesa, California. Respondent Pharmacy primarily dispenses diabetic test strips, test meters, lancets and lancing devices, and topical creams. The Board received multiple complaints alleging Preferred Pharmacy cold-called patients in an attempt to fill prescriptions, and/or filled patient prescriptions, without authorization. Board investigations confirmed that Respondent Pharmacy cold-called patients, test-billed prescriptions, filled prescriptions without patient knowledge, and utilized an unlicensed call center to solicit potential patients to fill prescriptions.

29. Respondent La was the Pharmacist in Charge (PIC) of Respondent Pharmacy from February 1, 2017 to October 7, 2019.

30. Respondent Agbassi was the PIC of Respondent Pharmacy since October 3, 2019 until present.

31. Respondent Montgomery owns and operates a variety of businesses and pharmacies including Respondent Pharmacy, located at 2202 Harbor Blvd., Suite D, Costa Mesa, California. Respondent Montgomery is not a licensed pharmacist. RXMSO is an entity associated with

Respondent Montgomery and is located in the same building complex as Respondent Pharmacy. The Board received information that RXMSO had call centers located in California, Florida, and the Philippines. RXMSO hired affiliates that obtained patient information and sold the information to RXMSO.

COMPLAINTS TO THE BOARD

32. On or around April 4, 2018, the Board received a complaint from Pharmacist MK on behalf of a homeless patient. The patient required daily insulin and any delay in the ability to test her blood sugar could result in hospitalization. The patient learned that she could not refill her prescription for diabetic test strips through her insurance because Respondent Pharmacy previously completed and billed her insurance for the prescription test strips. The patient did not request nor receive diabetic test strips from Respondent Pharmacy and had no knowledge that the prescription was placed on her behalf. Pharmacist MK researched Respondent Pharmacy's location and determined that Respondent Pharmacy was approximately 150 miles away from the patient. Pharmacist MK called Respondent Pharmacy and was informed that Respondent Pharmacy received signature confirmation for delivery. Pharmacist MK believed that this signature could not be the patient's signature as the patient was homeless.

33. On or about September 21, 2018, the Board received an anonymous complaint alleging that a patient received a telephone call from Respondent Pharmacy. The anonymous complainant stated that the caller asked the patient to describe their pain and to provide the name of the patient's care provider so that Respondent Pharmacy could call the provider and initiate prescriptions. The patient did not know how Respondent Pharmacy received the patient's information and did not provide the requested information.

34. On or about April 17, 2020, the Board received a complaint from a former employee of RXMSO. The employee, identified as YM, believed Respondent Montgomery operated RXMSO. YM confirmed RXMSO worked with approximately seven pharmacies including Respondent Pharmacy. YM stated that Respondent Pharmacy held patient information without patient authorization. YM alleged that RXMSO employed call center agents in the Philippines, Florida, and California. None of the agents was a licensed pharmacist or pharmacy technician.

YM stated that the call centers initiated contact with prospective patients and identified themselves as "with the Health Care Department." The agent offered prospective patients such things as cookbooks or coupons for free meals to obtain patient information, including the patient's full name, date of birth, treating physician information, and last four numbers of the patient's social security number.

35. On or around September 9, 2020, the Board received an online complaint from MI, a nurse practitioner for Sutter Health. MI stated that he received a prescription request for a Medicare patient, TW, from Respondent Pharmacy. MI indicated that the patient had never been to, nor requested services from, Respondent Pharmacy.

BOARD INVESTIGATIONS

36. Based on the complaints, the Board conducted investigations and inspections of Respondent Pharmacy.

37. On or around March 6, 2019, Board Inspectors BM and CW conducted an inspection of Respondent Pharmacy located at 3303 Harbor Blvd., Suite H7, Costa Mesa, California. Respondent La assisted in the inspection. The pharmacy stocked UPS boxes and UPS label sleeves. The pharmacy's stock was comprised mostly of topical creams and diabetic products. The pharmacy Daily Fill Log appeared to be mostly diabetes supplies, including over the counter alcohol pads, lancets, meters, and strips. Inspector BM noted that one computer monitor had a screen that stated, "Allow Remote Control" and "Control Remote Computer." Respondent La confirmed that Respondent Pharmacy held an Arizona non-resident pharmacy license. Board Inspector BM viewed an expired Nevada Pharmacy license on the wall.

38. During the inspection, Board Inspectors BM and CW issued corrections for the following violations:

a.) California Code of Regulations 1707.5(d), for the pharmacy not having interpretive services;

b.) California Code of Regulations 1714(c), for the pharmacy not having a sink with hot water;

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c.) California Code of Regulations 1715.65(c), for the pharmacy not having completed an inventory reconciliation of Schedule II controlled substances; and

d.) Business and Professions Code 4070(a), for e-fax prescriptions not being reduced to hard copy form and maintained.

39. As part of the inspection, Inspector BM interviewed Respondent La who stated the following:

a.) Respondent Montgomery knew more about the pharmacy procedures than Respondent La.

b.) Respondent La did not know about the marketing procedures and did not know if Respondent Pharmacy cold-called patients.

c.) Respondent Pharmacy received prescriptions via e-script or e-fax and automatically placed patient prescriptions on auto refill.

d.) E-scripts came directly from the prescribers via a Faxage server.[1] Inspector BM could not locate printed E-faxed prescriptions.

e.) Respondent Pharmacy used a delivery driver and did not mail prescriptions. Approximately half of Respondent's patients walked into the premises to fill prescriptions and prescriptions were set for auto refills. Respondent La did not know exactly how the prescriptions were delivered to locations several hours from Respondent Pharmacy's location.

40. Inspector BM asked Respondent La to log into Respondent Pharmacy's computer system. Respondent La could not log in to the fax server and called Respondent Montgomery. Once Respondent La gained access, Board Inspector BM reviewed prescriptions received by fax. The system organized prescriptions by the prescriber fax number and date/time. While reviewing Respondent Pharmacy's prescriptions, Board Inspector BM found:

a.) Respondent Pharmacy stocked preprinted prescriptions that appeared to be created by Respondent Pharmacy or a marketing company and included a fine print disclaimer

[1] A faxage server is a third-party faxing vendor fax that collects the prescriptions from doctors which then gets entered into a computer system, instead of the prescription being sent directly to the pharmacy.

that the prescriber's signature authorized the pharmacy to "substitute as necessary any comparable cream formulation, patch, gel, or kit."

b.) Inspector BM pulled two examples of preprinted prescriptions. One prescription was for Patient RD for lidocaine 5% ointment with three refills, and the other prescription was for CP for calcipotriene 0.005% cream with 5 refills. The prescriptions appeared to be created by Respondent Pharmacy or a marketing group and requested the prescription be faxed back to an unidentified toll free number. The prescriptions contained a disclaimer in fine print at the bottom that indicated that the prescriber's signature authorized the pharmacy to "substitute as necessary any comparable cream formulation, patch, gel, or kit."

c.) A review of Patient TW's file included a pre-printed fax that appeared to have been created by Respondent Pharmacy, although the prescription did not include the pharmacy name. The prescription included preprinted information such as the patient name, address, date of birth, and the prescriber name, address, phone number, fax number, and National Provider Identifier (NPI). The prescription advised the prescriber to fax the prescription back to an unidentified toll free number. The prescription contained generic prescriptions of diabetic test strips, lancets, alcohol prep pads, lancet device, glucose meter, control solution, and syringes, all with a 90-day quantity or single device listed in the quantity. The prescription included a section for refills, but three refills appeared to be already electronically circled on the prescription. The prescription was signed and dated June 24, 2017, however a signature log for the patient was not retrievable during inspection. Patient TW resided in Bakersfield. Respondent La stated that distant deliveries used a different system and that he did not have access to that system.

d.) Respondent La could not pull additional sample signatures for delivery when asked to do so by Board Inspector BM.

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Marketing Relationship with RXMSO

41. RXMSO is an entity associated with Respondent Montgomery and is located in the same building complex as Respondent Pharmacy. RXMSO includes a call center that contacted prescribers and patients to obtain prescriptions, demographics, and insurance information and access pharmacy systems to upload patient and prescription information on behalf of Respondent Pharmacy. There was no pharmacist overseeing RXMSO.

42. RXMSO company training documents included a coverage check process, a script for calling patients, RXMSO training, and a store contact list. The training document described the "Doc Chase" process, where after the pharmacy "approves a prescription," the RXMSO employee would attempt to obtain a prescription from the provider. Training documents included a prepared script for the employee to use when calling the prescriber. The training material instructed the employee to attempt to obtain a prescription by contacting the prescriber twice a day for approximately seven days. The documents described another process, the "Reverse Que," in which the agent would reverse or "credit return" billed prescriptions and then rebill them. The materials used by RXMSO were provided to employees of Respondent Pharmacy.

43. Beginning with the COVID-19 pandemic, call center employees worked from home. RXMSO affiliates cold-called patients and identified themselves as from the "health department." Once the affiliates obtained patient information, "coverage checkers" verified prescription profitability. If patients requested refills of prescriptions deemed "not profitable" to the pharmacy, the pharmacy would inform the patient "their insurance was telling the pharmacy to have the patient use a local community pharmacy" even though the pharmacy had not spoken with the patient's insurance company. If the claim was approved, the patient would move to the "doc chase" department. Members of the "doc chase" department would call prescribers and inform the prescriber that they previously spoke with the patient, even though the "doc chase" employee had not spoken with the patient. The "doc chase" employees received commissions based on how many prescriptions they obtained.

44. On or around August 19, 2020, Board Inspectors traveled to Respondent Pharmacy to tour the call center and to conduct a follow up interview of Respondent Agbassi. Respondent

Agbassi indicated that the call center ceased onsite operations and that he did not have access to the call center space. Respondent Agbassi stated that the company recently downsized and had only one call center employee. Respondent Agbassi believed Respondent Montgomery previously had access to the call center and oversaw the operations on occasion.

45. During the Board investigator's interview with Respondent Agbassi, Respondent Montgomery arrived. Inspector BM interviewed Respondent Montgomery. Respondent Montgomery admitted that Respondent Pharmacy bought patient leads from a marketer, or Management Services Organization in this case, RXMSO. The call center employed approximately five employees who worked from home due to COVID-19 shelter-in-place orders.

Test Billing and Solicitation of Prescriptions

46. A review of Respondent Pharmacy's data indicated as follows:

a.) The data was comprised of approximately 50,000 prescriptions.

b.) Respondent Pharmacy marked approximately 31,680 prescriptions as "completed."

c.) Respondent Pharmacy reversed billing in approximately 18,318 prescriptions, resulting in approximately 37% of prescriptions being cancelled.

d.) Respondent Pharmacy data reflected that there were approximately 5,333 patients who only had prescriptions that were in cancelled status, indicating that Respondent Pharmacy typed and attempted to process prescriptions for 5,333 patients for whom Respondent Pharmacy had never filled prescriptions. This is a red flag that indicated Respondent test billed prescriptions, that is, Respondent Pharmacy submitted fraudulent insurance claims to determine if the prescription would result in a profit for the pharmacy.

e.) Data from February 1, 2017, through October 7, 2019, indicated that Respondent La verified approximately 30,323 prescriptions as PIC, while Respondent Agbassi verified approximately 976 prescriptions as PIC. Over 18,000 prescriptions did not list a pharmacist in the verified by column, indicating no pharmacist reviewed or dispensed the prescription.

f.) Although Respondent La alleged that Respondent Pharmacy only utilized a delivery driver for delivering prescriptions, Respondent Pharmacy held prescriptions for patients from 821 separate California cities. Respondent Pharmacy only completed approximately 30 prescriptions in Costa Mesa, where Respondent Pharmacy was located, representing 0.11% of Respondent's prescriptions. The top cities where Respondent Pharmacy completed prescriptions are as follows:

Patient City	Distance from Costa Mesa (approximate miles)	Count of Rx Number	Percentage of Total Rx's
Sacramento	427	1894	5.98%
Los Angeles	41	1591	5.02%
Fresno	261	1294	4.08%
San Diego	87	850	2.68%
Bakersfield	154	814	2.57%
Long Beach	28	646	2.04%
Modesto	354	592	1.87%
Lancaster	113	549	1.73%
San Bernardino	56	424	1.34%
Victorville	88	413	1.30%

47. Dr. LM appeared in approximately 2,489 prescriptions. Of these prescriptions, approximately 2,445 prescriptions were cancelled and only 44 were completed. Dr. LM's address of record was approximately fifty miles from the pharmacy. The patients listed as Dr. LM's "patients" resided throughout the state and not near Respondent Pharmacy nor Dr. LM's office. Dr. LM's office confirmed via questionnaire that out of the approximately 2,445 prescriptions provided by Inspector BM, only 19 of those patients ~~(27 total prescriptions)~~ were under Dr. LM's care. The remaining approximately 2,171 separate patients had prescriptions created by Preferred Pharmacy that were not patients of Dr. LM. Thus, approximately 2,426 separate prescriptions were created by Preferred Pharmacy using Dr. LM's name. Dr. LM stated that he had not authorized the pharmacy to create prescriptions for the patients that were not his patients. Dr. LM did note that he had sent some prescriptions to the pharmacy for the 19 patients under his care but stated that Respondent Pharmacy test billed approximately 2,426 prescriptions under Dr. LM's name without his authorization.

48. Dr. DS confirmed that Respondent Pharmacy test billed 56 prescriptions that were not authorized. Dr. DS stated that he was not familiar with Respondent Pharmacy, did not prescribe these types of prescriptions (test strips, lancets, alcohol pads), had not authorized Respondent Pharmacy to test bill prescriptions under his name, and that the patients on the list of prescriptions provided were not his patients. Dr. DS's office confirmed 56 prescriptions had not been authorized by the prescriber.

49. Dr. DD confirmed that he did not authorize approximately 19 prescriptions that were test billed by Respondent Pharmacy. Dr. DD retired on January 25, 2019, and he confirmed that he did not write any prescriptions after that date. Additionally, Dr. DD stated that he was not familiar with Respondent Pharmacy, was located more than 500 miles from Respondent Pharmacy, did not perform telemedicine, and only saw patients in person. Thus, it was unlikely that he authorized any prescriptions for patients located outside of Paradise, California.

50. An employee of Respondent Pharmacy and RXMSO confirmed that Respondent Pharmacy test billed prescriptions to ensure that the prescriptions were profitable. The employee explained that if Respondent Pharmacy could make $35.00 from the patient's prescription, then it would pursue obtaining the prescription. The employee confirmed that if the patient wanted a refill or a prescription but the profit was less than $35.00, or if the patient had a high copay, Respondent Pharmacy would lie to the patient and tell the patient that their insurance informed Respondent Pharmacy to have the patient use a local community pharmacy instead.

51. Inspector BM contacted patients that received prescriptions from Respondent Pharmacy. Responding patients indicated that Respondent Pharmacy billed their insurance in some instances, that they received cold calls in an attempt to obtain authorization to bill and obtain prescriptions for the patient, that they had not contacted Respondent Pharmacy directly to fill prescriptions. By way of example, the following patients stated the following:

a.) Patient DJ stated that she received supplies from Respondent Pharmacy that she had not requested. She had not been to the pharmacy and did not know how Respondent Pharmacy obtained her information. Patient DJ confirmed that she was cold-called by

Respondent Pharmacy. She further confirmed that she did not authorize Respondent Pharmacy to bill her insurance.

b.) Patient RP indicated that she received prescriptions from Respondent Pharmacy but that she had not been to, did not provide a prescription to, and did not know how Respondent Pharmacy obtained her contact information. Patient RP confirmed that Respondent Pharmacy cold-called her.

c.) Patient JM stated that he had not received or requested prescriptions from Respondent Pharmacy. Patient JM stated that he did not authorize Respondent Pharmacy to bill his insurance. Patient JM's prescription was listed as "cancelled" in the computer system.

d) Respondent Pharmacy declined to fill a prescription for S.O. after her insurance changed and the pharmacy noted "New Insurance no longer meets margin, will D/C Patient In Pioneers" according to a screenshot provided.

52. On or around November 21, 2019, Respondent La participated in a conference call with Board Inspectors and confirmed that Respondent Pharmacy used "RXMSO" employees known as "chasers." Contrary to what Respondent La previously stated, Respondent Pharmacy mailed about 90% of the prescriptions. Patients called and asked why they received prescriptions from Respondent Pharmacy. "RXMSO" staff that called these patients were different from the "chasers." Respondent Pharmacy sometimes received returns from patients. Those prescriptions were returned for destruction and reversed from billing. Respondent La explained the prescription would be filled typically by him, given to the clerk who would label it for shipping, and the driver would collect the boxes for delivery via "DCS."

Adulterated Prescriptions

53. Respondent Pharmacy accepted prescriptions returned by patients. If a patient returned a prescription, Respondent Agbassi would reverse the insurance charge and examine the product. If the product appeared intact and still sealed, Respondents would re-dispense the product despite having no knowledge of the conditions in which the products were kept.

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Lack of Pharmacy Security

54. On or around September 9, 2019, Inspector BM conducted another inspection of Respondent Pharmacy. Upon entering the pharmacy, Inspector BM found that two clerks and pharmacy technicians EL and YT were present in the pharmacy with computers running and patient profiles visible on one screen and without a pharmacist present. Pharmacy technicians possessed keys to enter the pharmacy. Although the pharmacy maintained a small stock of dangerous drugs in the front locked room, test strips, pharmacy computers, and patient prescriptions were located in the main pharmacy area.

FIRST CAUSE FOR DISCIPLINE

(Interference with Pharmacist in Charge

Against Respondent Pharmacy and Respondent Montgomery)

55. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301 subdivision (o), for violating California Code of Regulations, title 16, section 1709.1, subdivision (b), and Code section 4330, subdivision (b), in that Respondent Pharmacy and Respondent Montgomery utilized an unlicensed, offsite call center to contact patients and prescribers; maintained fax servers to receive prescriptions that the Pharmacist-in-Charge could neither access nor locate; and, used delivery systems that the Pharmacist-in-Charge did not have knowledge of, access to, nor control over, as described above in paragraphs 28 through 54 which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Unlicensed Activity Against All Respondents)

56. Respondents are subject to disciplinary action under Code sections 4301, subdivision (o), for violating Code section 4110, subdivision (a), in that Respondents utilized an unlicensed entity, RXMSO, to run a call center to contact prescribers and patients to obtain prescriptions and access pharmacy systems to upload patient and prescription information. This location was not supervised by a pharmacist and was not licensed by the Board, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

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THIRD CAUSE FOR DISCIPLINE

(Unauthorized Disclosure of Prescription Information

Against Respondent Pharmacy and Respondent Montgomery)

57. Respondents are subject to disciplinary action under Code sections 4301 subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1764, and California Civil Code section 56.10, subdivision (a), in that Respondent Pharmacy and Respondent Montgomery ran an unlicensed call center that contacted prescribers and patients to obtain prescriptions, demographics, and insurance information and accessed pharmacy systems to upload patient and prescription information. The call center was not supervised by a pharmacist and was manned by unlicensed staff, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Insurance Fraud Against All Respondents)

58. Respondents are subject to disciplinary action under Code sections 4301 subdivisions (j) and (o), for violating Code section 810, subdivision (b) and Penal Code section 550 subdivision (a)(6) and (7), in that Respondent Pharmacy knowingly made or caused to be made any false or fraudulent claim for payment of a health care benefit and knowingly submitted a claim for a health care benefit that was not used by, or on behalf of, the claimant. Specifically, and as more fully set forth in paragraphs 46 through 52 above, between February 1, 2017, and November 7, 2019, Respondents cancelled 18,318 prescriptions in the computer system and had approximately 5,333 patients who only had prescriptions that were in the cancelled status (the pharmacy entered a prescription for them but never dispensed drugs or products). These 18,318 claims represented approximately 37% of Respondent Pharmacy's typed prescriptions and suggests that Respondent Pharmacy was test-billing and soliciting prescriptions it knew it would not be dispensing. Additionally, patients confirmed that Respondent Pharmacy cold-called patients and billed their insurance either without the patient's authorization and/or without the patient requesting prescriptions be filled by Respondent Pharmacy.

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FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct Against All Respondents)

59. Respondent Pharmacy is subject to disciplinary action under Code sections 4301 subdivisions (f), (g) and (o) in that Respondent Pharmacy test-billed insurance claims the patient did not receive, billed patient's insurance without authorization, ran an unlicensed call center that accessed patient prescription information, cold-called patients, and lied about cold calling patients, as described above in paragraphs 44 through 52, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Subverting an Investigation

Against Respondent Pharmacy, Respondent Montgomery and Respondent La)

60. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301, subdivision (q), in that Respondent Pharmacy, Respondent Montgomery and Respondent La each signed a written statement denying that patients were cold-called, stating that pharmacy personnel delivered prescriptions despite prescriptions being shipped hundreds of miles away, and denying that marketers had access to pharmacy records despite marketers calling patients and prescribers regarding their prescriptions, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by a Corporation

Against Respondent Pharmacy and Respondent Montgomery)

61. Respondent Pharmacy and Respondent Montgomery are subject to disciplinary action under Code sections 4301, subdivision (o), in conjunction with Code section 4156 in that Respondent Pharmacy and Respondent Montgomery test-billed insurance claims for prescriptions the patients did not receive, billed patients' insurance without authorization, ran an unlicensed call center that accessed patient prescription information, cold-called patients, and lied about cold calling patients, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Obstruction of Prescriptions Against All Respondents)

62. Respondents are subject to disciplinary action under Code sections 4301, subdivisions (f) and (o), and Code section 733, subdivision (a) and (b), in that Respondents' policies and procedures confirmed the pharmacy would not ship a patient their prescription if the prescription did not meet a set profit margin, including if the patient was receiving a refill for a prescription previously filled by the pharmacy. In addition, Respondents declined to fill prescriptions for Patient SO after her insurance changed and her file noted "new insurance no longer meets margin," as described above in paragraphs 28 through 54, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Adulterated Drugs Against all Respondent Pharmacy and Respondent Agbassi)

63. Respondent Pharmacy, Respondent Montgomery and Respondent Agbassi are subject to disciplinary action under Code sections 4301, subdivision (j), Code section 4169, subdivision (a)(1) and (2), and Health and Safety Code sections 111255 and 111295 in that Respondents sold, delivered, held, or offered for sale an adulterated drug, as described above in paragraphs 28 through 54, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Lack of Pharmacy Security

Against Respondent Pharmacy and Respondent Agbassi)

64. Respondent Pharmacy, Respondent Montgomery and Respondent Agbassi are subject to disciplinary action under Code sections 4301 subdivision (j), Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that non-pharmacist personnel had a key to the pharmacy premises, which allowed access to pharmacy computer systems and records an hour prior to the arrival of the pharmacist, as described above in paragraph 54, which is incorporated herein by reference.

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OTHER MATTERS

65. Pursuant to Section 4307, if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, Respondent Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

66. Pursuant to Section 4307, if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, and Respondent Agbassi, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 54453 was revoked, suspended, or placed on probation, Respondent Agbassi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

67. Pursuant to Section 4307, if Pharmacy Permit Number PHY54453 issued to Preferred Pharmacy, Inc. is suspended, revoked or placed on probation, and Respondent Montgomery, while acting as the manager, administrator, owner, member, officer, director, associate, or partner, had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number PHY 54453 was revoked, suspended, or placed on probation, Respondent Montgomery shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee of the Board.

68. Pursuant to Section 4307, if Pharmacist License Number RPH 73904 issued to Tony Hieu La is suspended or revoked, Respondent La shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

69. Pursuant to Section 4307, if Pharmacist License Number RPH 80700 issued to Michael Jean Olivie Agbassi is suspended or revoked, Respondent Agbassi shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Permit Number PHY 54453, issued to Preferred Pharmacy, Inc.; Scott Leroy Montgomery, CEO;

2. Revoking or suspending Registered Pharmacist License Number RPH 73904, issued to Tony Hieu La;

3. Revoking or suspending Registered Pharmacist License Number RPH 80700, issued to Michael Jean Olivie Agbassi;

4. Ordering Tony Hieu La, Michael Jean Olivier Agbassi and Scott Leroy Montgomery to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

5. Prohibiting Preferred Pharmacy, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54453 is placed on probation or until Pharmacy Permit Number PHY 54453 is reinstated if Pharmacy Permit Number PHY 54453 issued to Preferred Pharmacy is revoked;

6. Prohibiting Scott Montgomery from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54453 is placed on probation or until Pharmacy Permit Number PHY 54453 is reinstated if it is revoked;

7. Prohibiting Tony Hieu La from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 73904 is placed on probation or until Registered Pharmacist License Number RPH 73904 is reinstated if it is revoked; and,

8. Prohibiting Michael Jean Olivie Agbassi from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Registered Pharmacist License Number RPH 80700 is placed on probation or until Registered Pharmacist License Number RPH 80700 is reinstated if it is revoked; and,

9. Taking such other and further action as deemed necessary and proper.

DATED: 8/31/2022

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2022.08.31 19:49:25 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Section 1: General Information

First: Morgan Middle: Alexis Last: Miller

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted] Twisted Pine Ave

City: Las Vegas State: NV Zip: 89131

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: Northwest Career College

Address: 7398 Smoke Ranch Rd

City: Las Vegas State: NV Zip: 89178

Name of Program Director: Samantha Huntsman

Signature of Program Director: [signature]

Section 3: Employment Information

Pharmacy Name: License #:

Address:

City: State: Zip:

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	Yes	No
1. Are you 18 years of age or older?	X	
2. Are you a high school graduate or the equivalent?	X	

High School Name: Arbor View High School Graduation Date OR Date GED obtained (mm/yy): 06/2012

Address: 7500 Whispering Sands Dr

City: Las Vegas State: NV Zip: 89131

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 7: Personal and Professional History	Initials	
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: **WARNING** **You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.**	M.M	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?	X	
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?		X
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		X
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Morgan Milk

Original Signature (electronic, copies or stamps not accepted)

12/05/23

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Morgan Miller

Print Name

Morgan Miller

Original Signature (electronic, copies or stamps not accepted)

12/05/23

Date

Board Use Only	Date Received: 12/13/23	Amount: $50 - check #957350841

Amethyst Recovery Center

Morgan Miller ♀ 2023-201

Birthdate: [redacted] Bed: 105-A

Allergies: No Known Allergies/NKA

Admission: 03/16/2023 Care Team

Location: Amethyst Recovery Center, LLC
Detox
(GMT-05:00) America/New_York

Lab Reports

Lab Report

Specimen	Accession No	Reported At
KGPFAHFK	1229359	04/10/2023 03:30 PM
Collected At	Results For Review:	
04/07/2023 12:29 PM	[redacted]	
Results Summary: Normal: 15		

Assigned By:	Unassigned By:
Automatic System Task at 04/10/2023 03:49 PM	N/A

Patient

First Name	Middle Name
MORGAN	N/A

Last Name	MR Number	Date Of Birth	Phone
MILLER	2023-201	[redacted]	[redacted]

Address	Gender	Payment Method	Location
[redacted] Twisted Pine Avenue Las Vegas NV 89131 , US	Female	N/A	Amethyst Recovery Center, LLC Detox

Current Diagnoses

F10.239 Alcohol dependence with withdrawal, unspecified; F10.20 Alcohol use disorder, Severe; F17.290 Nicotine dependence, other tobacco product, uncomplicated; F31.4 Bipolar disorder, current episode depressed, severe, without psychotic features; F41.1 Generalized anxiety disorder; G40.909 Epilepsy, unspecified, not intractable, without status epilepticus; L40.9 Psoriasis, unspecified; R53.81 Other malaise; Z11.1 Encounter for screening for respiratory tuberculosis; Z11.3 Encounter for screening for infections with a predominantly sexual mode of transmission; Z11.4 Encounter for screening for human immunodeficiency virus [HIV]; Z20.5 Contact with and (suspected) exposure to viral hepatitis; Z71.6 Tobacco abuse counseling; Z32.02 Encounter for pregnancy test, result negative; Z71.3 Dietary counseling and surveillance; Z72.4 Inappropriate diet and eating habits

Lab

Name

SCIENTIFIC LABORATORY COMPANY,LLC

CLIA Code

10D2106985

Address

3395 Lake Worth Road Suites 1 Palm Springs FL , US

Phone

561-855-2479

Director

Dr. Craig Deligdish

Reported Medical Tests

Test Description	Status	Specimen Source	Received At
URINE DRUG SCREEN BY EIA w/REFLEX	Final Result	UR: Urine	04/07/2023 04:42 PM
		Completed At	Ordering Physician
		04/10/2023 03:30 PM	Jeffrey Bishop

Lab
N/A

Results

Result Description	Observed Result	Observed At	Cutoff / Reference Range	Unit	Outcome	Status	Lab
AMPHETAMINES	NEGATIVE	04/10/2023 03:30 PM	500.0 CUTOFF	ng/mL	Normal	Final	N/A

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13A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Dispensing Practitioner Registration Application
Non-Refundable $300 fee

Rev (06/16/2022)

Type of Application

- ☒ New Dispensing Location
- ☐ Dispensing Location Ownership Change (Provide current Dispensing Registration #: _____)
- ☐ Dispensing Location Address Change (Provide current Dispensing Registration #: _____)

What types of drug(s) will you be dispensing?

- ☐ Dangerous Drugs (DD) ONLY
- ☒ Dangerous Drugs (DD) AND Controlled Substances (CS) (Provide your Controlled Substance Registration #: CS06509)

Is the office or facility from which the practitioner intends to dispense DD/CS wholly owned and operated by the practitioner?

- ☒ Yes
- ☐ No (Facility owner(s) must complete the Personal History application at www.bop.nv.gov. Submit this with your application.)

Section 1: Personal Information

First: David Middle: _____ Last: Lanzkowsky

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted] Paradise Road Apt 103

City: Las Vegas State: NV Zip: 89109

Telephone: [redacted] Email: kmerrill@cprnlv.com

Degree: M.D. Practitioner License #: 6468 Specialty: Interventional Pain Management

(You MUST have a current and active license with your respective BOARD to apply for and maintain a practitioner dispensing registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: Centennial Medical Group

Practice Address: 2110 E Flamingo Rd Suite #: _____

City: Las Vegas State: NV Zip: 89119

Telephone: _____ Fax: _____ Email: _____

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
		NV	Las Vegas	Clalrk
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
23-106		Nevada State Board of Pharmacy		
Reason/Charge				
Pending case				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
David Lanzkowsky, M.D.				
Name of Business/Industry/Entity				

Provide explanation below:

Case still pending regarding schedule 2 prescribing

Original Signature (electronic, copies or stamps not accepted)

8-18-2023
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered dispensing practitioner who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

David Lanzkowsky, M.D.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-18-2023

Date

Board Use Only: Date Processed: _____ Amount: 300 CC

14

14A

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☐ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☒ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)

Select the Controlled Substance Schedules you are applying to prescribe

☒ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Chasity Middle: Denise Last: Beene

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted] Cardinal Lane

City: Florence State: AL Zip Code: 35634

Telephone: [redacted] Email: [redacted]

APRN License #: 868604 Specialty: Family

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: City of Las Vegas Detention Center - 5088

Practice Address: State (Nevada) 3300 Stewart Ave Suite #:

City: Las Vegas State: NV Zip: 89101

Telephone: 702 229-6508 Fax: Email: [redacted]

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☒ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X — 17yr sobr (tx 17yr ago)
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		X
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		X — not as CRNP (as RN)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1+4. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2002/2006	Active Released 2011	AL	Montgomery	Montgomery
Case #	Governing, licensing, Arresting Presiding Body/Agency/Court: Alabama Board of Nursing			
Reason/Charge: Suspected Substance Abuse.				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy: NA		
Name of Business/Industry/Entity				

Provide explanation below:

In 2002 my RN license was suspended. I entered treatment and completed all necessary requirements by the Alabama Board of Nursing, 2006 license was placed on probation for 5 years and after completion of the Program, I was released with No restrictions & Active RN license in 2011. I went Back to CRNP school in 2017 & obtained my NP license in 2019. I currently have 17 years of sobriety, continue to go to AA, have sponsor and work with other women in sobriety.

I will Enclose my ASN records & release letter.

I currently have DEA in Washington & Colorado & several other licence in other states & am working tele health in the jails with Inmates with Naphcare.

Chasity Beene

Original Signature (electronic, copies or stamps not accepted)

9/26/23

Date

Alabama Board of Nursing
Peggy Sellers Benson, MSN, RN, MSHA, NE-BC
Executive Officer

RSA Plaza, Suite 250
770 Washington Ave
Montgomery, AL 36104

www.abn.alabama.gov
(334) 293-5200
1-800-656-5318
Fax (334) 293-5201

Mailing address
P.O. Box 303900
Montgomery, AL 36130-3900

Chasity Beene
[redacted]

RE: ABN Records of: **CHASITY DENISE BEENE MARTIN**

Dear Sir or Madam:

Please find attached certified copies of documents that are considered public record regarding disciplinary action against the following nurse(s): **CHASITY DENISE BEENE MARTIN, LICENSE NUMBER: 1-099287.**

Should you need further information, please contact our office

Sincerely,

Patty Mills

Patricia A. Mills
Legal Research Assistant

/pam
Enclosures

Alabama Board of Nursing
Peggy Sellers Benson, MSN, RN, MSHA, NE-BC
Executive Officer

RSA Plaza, Suite 250
770 Washington Ave
Montgomery, AL 36104

www.abn.alabama.gov
(334) 293-5200
1-800-656-5318
Fax (334) 293-5201

Mailing address:
P.O. Box 303900
Montgomery, AL 36130-3900

BEFORE THE ALABAMA BOARD OF NURSING

STATE OF ALABAMA)

MONTGOMERY COUNTY)

I, Peggy Sellers Benson, RN, MSHA, MSN, NE-BC, Executive Officer of the Alabama Board of Nursing, do hereby certify that I am the legal Custodian of Records for the Alabama Board of Nursing and that the attached are in record and on file in my office at Suite 250, RSA Plaza, 770 Washington Avenue in the City of Montgomery, County of Montgomery, State of Alabama, that the laws of the State require said records be kept and that the same are true and correct copies of said originals **CHASITY DENISE BEENE MARTIN.**

WITNESS my hand and seal of the Alabama Board of Nursing on the 14th day of April, 2023.

ALABAMA BOARD OF NURSING

Peggy S Benson

PEGGY SELLERS BENSON RN, MSHA, MSN, NE-BC
EXECUTIVE OFFICER

ALABAMA BOARD OF NURSING

RSA Plaza, Ste 250
770 Washington Ave
Montgomery, AL 36104

Mailing Address:
P.O. Box 303900
Montgomery, AL 36130-3900

(334) 242-4060
1-800-656-5318
Fax (334) 242-4360

N. Genell Loe, MSN, RN, JD
Executive Officer
www.abn.alabama.gov

October 6, 2011

CHASITY DENISE BEENE
[redacted] MEREDITH DRIVE
MUSCLE SHOALS AL 35661

IN REPLY PLEASE REFER TO:

In The Matter Of:
License Number #: 1-099287

Dear Ms. Beene:

Your file has been reviewed for determination of your compliance with the Board's Order of March 24, 2006. Your probation status was cleared effective today. If you would return your wallet RN license card another one will be issued to you.

On behalf of the Board, we extend our best wishes for your future nursing career and personal endeavors. If we can ever be of assistance, do not hesitate to call.

Sincerely,

Dawn B. Daniel

Dawn B. Daniel, MSN, RN
Nurse Consultant
Probation/Monitoring

DBD:vm

BEFORE THE ALABAMA BOARD OF NURSING

IN THE MATTER OF:	)	
	)	
CHASITY DENISE BEENE MARTIN	)	**CONSENT ORDER**
	)	
LICENSE NO. 1-099287	)	

The Alabama Board of Nursing, hereinafter referred to as Board, having evidence that **CHASITY DENISE BEENE MARTIN**, hereinafter referred to as Respondent, is in violation of the Code of Alabama 1975, § 34-21-25, and the Alabama Board of Nursing Administrative Code, § 610-X-8; and Respondent, desiring to avoid the necessity of a formal hearing, do hereby enter into this Consent Order in lieu of proceeding with further disciplinary action. Respondent understands the right to a formal hearing in this matter and hereby knowingly waives such right. Respondent further understands and agrees that this is a non-appealable Order.

FINDINGS OF FACT

I.

On April 22, 2003, Respondent was licensed by the Alabama Board of Nursing as a Registered Nurse and was so licensed at all times relevant to matters stated herein. Respondent is currently licensed through December 31, 2006.

II.

On September 25, 2005, Respondent reported to work as a RN at Walker Baptist Medical Center, Jasper, Alabama, while under the influence of unknown chemicals. Respondent was described as stumbling, appearing disoriented, acting strange and almost falling out of a chair.

Multiple patients reported concerns about the Respondent's care as follows: failure to administer medications, dropping the MAR, and spilling water on a patient.

A urine drug screen conducted for cause was positive for methamphetamine and amphetamine. Respondent did not have a valid prescription for either drug. Respondent attributed her conduct to the one time use of methamphetamine prior to going to work.

CONCLUSIONS OF LAW

The conduct stated above constitutes sufficient grounds for the imposition of sanctions against Respondent's license to practice as a Registered Nurse in the State of Alabama pursuant to the Code of Alabama 1975, § 34-21-25, and the Alabama Board of Nursing Administrative Code, § 610-X-8-.03(4)(a)(e); (6)(a)(b)(f)(i)(ii)(iii)(m)(q)(v)(x).

ORDER

Respondent's Alabama Registered Nurse License, No. 1-099287, is hereby **SUSPENDED** until such time as the Board is in receipt of documentation of: (a) completion of required evaluations in accordance with Stipulation Number 4 below; (b) successful completion of the initial phase of an approved treatment program as specified in Stipulation Number 6 below, if treatment is recommended; (c) participation in an aftercare program as specified in Stipulation Number 7 below, if treatment is recommended; (d) negative random monthly drug screens as specified in Stipulation Number 15 below; (e) active participation in Twelve Step Programs as specified in Stipulation Number 9 below, if recommended; (f) accrual of requisite continuing education contact hours; and, (g) payment of appropriate fees. Should Respondent be deemed in need of treatment and upon documented completion of the above terms, Respondent's license will be reinstated on **PROBATION** for sixty (60) months pursuant to the following terms and conditions. If not deemed to be in need of treatment, Respondent's license will be placed on probation for twelve (12) months pursuant to the terms and conditions in this Order. In no event

will this period of suspension extend longer than TWELVE (12) MONTHS past the effective date of this Order. Should such occur, Respondent's licensure status will be considered as and listed as revoked.

1. **Return of Wallet ID Card**

Respondent's wallet ID card shall be **immediately** returned to the Alabama Board of Nursing office. Upon reinstatement, Respondent will be issued a wallet ID card which indicates probationary status.

2. **Fine**

Respondent shall pay a fine in the amount of **$750** if treatment is recommended or **$250** if treatment is not recommended. This fine must be paid within thirty (30) days of the effective date of Respondent's reinstatement. Respondent understands that failure to pay the fine is cause for additional disciplinary action by the Board of Nursing.

Should Respondent's probation extend beyond a period of thirty-six (36) months, Respondent shall pay an additional fine of $250 prior to termination of this Order.

3. **Education – Completion of Course**
(If not deemed in need of chemical dependency treatment)

Respondent shall satisfactorily complete a Board-approved course/program on chemical dependency and provide documentation of completion to the Board. This course must be satisfactorily completed within three (3) months of the effective date of this Order.

4. **Evaluations (Chemical dependency)**

Respondent must submit the results of required comprehensive evaluations for chemical dependency, physical and mental illness from a Board-recognized treatment provider with Board consultation with the evaluating professional prior to making the assessment. Respondent must abide by any requests and recommendations from the providers that may include inpatient evaluation, outpatient evaluation, partial hospitalization evaluation and psychological testing.

Respondent is also required to undergo subsequent evaluations by a recognized provider with a healthcare professionals tract should such be requested by the Board following a relapse or for other cause. Respondent must follow all treatment recommendations from the provider including inpatient treatment, outpatient treatment, halfway house, residential long-term treatment, counseling, etc.

If not eligible for early release, the Respondent shall return to the original treatment provider(s) or other Board-approved provider for required comprehensive evaluations and a determination of readiness to practice without supervision and/or monitoring. Said evaluations must be performed within the ninety (90) day period immediately prior to the scheduled termination of this Order. Based upon the evaluations, the Board may extend the period of this Order and require additional treatment, counseling, etc.

5. **Duration of Order**

The duration of this Order is for a period of sixty (60) months unless extended pursuant to Stipulation Number 4 below. Respondent may apply for early release after thirty-six (36) months of satisfactory compliance with all the stipulations of this Order. If Respondent applies for early release, a comprehensive chemical dependency, physical and mental evaluation from a treatment provider with a healthcare professionals tract which supports early release shall be submitted to the Board. Said evaluation must be performed within the ninety (90) day period immediately prior to submission of the application for early release. The duration of this Order is for a period of twelve (12) months if deemed not in need of chemical dependency treatment. These time periods are subject to Stipulation Number 25 below.

6. **Treatment Program (If chemical dependency treatment recommended)**

The program must be a Board-recognized chemical dependency treatment program. Respondent shall cause the director of the treatment program to submit to the Board proof of Respondent's entry into a primary intensive alcohol/drug treatment program in accordance with the recommendations made during the evaluation process which may include inpatient treatment,

outpatient treatment, halfway house, residential long-term treatment and/or a combination thereof. Respondent shall also cause the program director to provide the Board with documentation concerning Respondent's successful completion of the program, readiness to return to the safe practice of nursing and recommendations and arrangements for appropriate follow-up.

7. **Aftercare Program (If chemical dependency treatment recommended)**

Unless otherwise recommended by the treatment provider and approved by the Board, the Respondent, within one (1) week of the completion of the initial phase of the treatment program, shall enter a Board-acceptable chemical dependency aftercare program with said program to meet on a weekly basis and to extend for a minimum of one (1) year. Respondent shall also cause the program to submit to the Board, in writing, and on the Board-approved form, documentation of the Respondent's attendance, participation and progress in the program. Such reports are due quarterly, according to schedule, for the duration of the probationary period or until successful completion of the aftercare program. In the event the Respondent is discharged from the aftercare program for noncompliance, the Respondent and the program are to immediately notify the Board, in writing, of such occurrence. This is required regardless of whether Respondent is employed in nursing.

8. **Individual/Group Counseling (If recommended by chemical dependency evaluation)**

Respondent shall participate regularly in a Board-acceptable counseling program contingent upon the recommendations of the original treatment program. Respondent shall continue in counseling for as long as deemed necessary by the counselor/therapist. This stipulation is in addition to meeting the stipulation requiring aftercare participation. Respondent shall have the counselor/therapist notify the Board when continued counseling is no longer indicated and Respondent is discharged or when there is a failure to complete or comply with the course of therapy. Respondent shall also cause the program to submit to the Board, in writing and on the Board-approved form, evidence of satisfactory participation and progress in counseling. Such reports are due quarterly, according to schedule, as long as indicated during

the period of this Order. This is required regardless of whether Respondent is employed in nursing.

9. **Twelve Step Meetings (If recommended by chemical dependency evaluation)**

Respondent shall attend and participate in a minimum of three (3) Twelve Step meetings per week for the duration of this Order. The Respondent shall submit meeting attendance verification sheets monthly, according to schedule, on the Board-approved form, for the duration of the Order period. It is required that Respondent have a sponsor during the period of this Order. If there is a sponsor, the Board should be provided sufficient information as how to contact this individual. This is required regardless of whether Respondent is employed in nursing.

10. **Self-Report**

Respondent shall submit a written status report to the Board on a Board-approved form. This is to be submitted on a monthly basis, according to schedule, and must contain a self-assessment of current status. This report is required regardless of whether Respondent is employed in nursing. At the Board's discretion, Respondent may be allowed to make verbal contact with Board staff in lieu of a written report.

11. **Primary Physician – Drug Use Exception**

The Respondent will have only one primary physician/group during the period of this Order. The primary physician must refer to any other physician, except in a documented emergency. All mood-altering medications or medications containing a mood-altering substance must be prescribed to Respondent by this primary physician for a bona fide medical condition, or if prescribed by the referred physician, must be immediately reported in writing by the Respondent to the primary physician with a copy to the Board. Respondent must notify the Board of the name, address, and telephone number of the primary physician within ten (10) days of the effective date of this Order and within ten (10) days in the case of a new physician. Respondent shall cause any and all prescriptions to be verified to the Board by the prescribing practitioner on a Board-provided form at the time of the issuance of a prescription and must also provide verification of all

medications prescribed prior to the Respondent's Board Order. No prescription over twelve (12) months old should be taken without an updated prescription verification. The Board or its designee may, at any time, request the practitioner to document the continued need for prescribed medications. Respondent shall keep a written record of medications taken, including over-the-counter drugs, and produce such record upon request by the Board. This is required regardless of whether Respondent is employed in nursing.

12. **Dentist – Drug Use Exception**

The Respondent will have only one dentist during the period of this Order. The primary dentist must refer to any other dentist or dental specialist, except in a documented emergency. All mood-altering medications or medications containing a mood-altering substance must be prescribed to Respondent by this primary dentist for a bona fide dental condition, or if prescribed by a referred dentist, must be immediately reported in writing by the Respondent to the primary dentist with a copy to the Board. Respondent must notify the Board of the name, address, and telephone number of the primary dentist within ten (10) days of the effective date of this Order. Respondent shall cause any and all prescriptions to be verified to the Board by the prescribing dentist on a Board-provided form at the time of the issuance of a prescription and must also provide verification of all medications prescribed prior to the Respondent's Board Order. No prescription over twelve (12) months old should be taken without an updated prescription verification. The Board or its designee may, at any time, request the practitioner to document the continued need for prescribed medications. Respondent shall keep a written record of medications taken, including over-the-counter drugs, and produce such record upon request by the Board. This is required regardless of whether Respondent is employed in nursing.

13. **Abstain from Alcohol Use**

Respondent shall abstain completely from the use of any substance containing alcohol.

14. **Abstain from Drug Use**

Respondent shall abstain completely from the non-prescribed use or possession of controlled substances as defined in the Alabama Uniform Controlled Substances Act, illegal drugs as defined by law, mood-altering substances, or any drugs requiring a prescription (legend) except as provided for in this Order.

15. **Drug Screening**

Respondent shall participate as directed in a Board-acceptable program for random drug testing. The drug screen will be a Board-approved drug screen and may include additional chemicals as designated by the Board or its designee. A minimum of one (1) random testing per month shall be done and may be required more frequently as requested by the Board or its designee. Further, the Board or its designee may at anytime require the Respondent to undergo additional drug screening of a type specified by the Board, including hair tests of a minimum of one time per year, to ensure that the Respondent is free of chemical substances. Refusal to provide a specimen suitable for testing within the requested time frame constitutes a violation of this Order and grounds for disciplinary action. Respondent waives any argument as to chain-of-custody of the sample or validity/accuracy of its testing regarding any positive screen received by the Board from an approved testing facility. The report of a positive drug screen which is not a result of documented, prescribed medications as provided for herein shall be considered a violation of this Order. This is required regardless of whether Respondent is employed in nursing.

16. **Employment - Monitoring**

Respondent shall practice only under the on-site monitoring of a Board-approved licensed health professional in good standing with their professional regulatory body. The employment monitor is not required to be on the same unit or ward as Respondent but should be on site and readily available to provide assistance and intervention in the event the Respondent appears impaired or otherwise unable to safely practice. The Respondent shall work only

regularly assigned, identified, and predetermined units. The on-site monitor shall be primarily one (1) person. The Respondent shall not be self-employed or contract for services.

17. **Employment-Increased Autonomy**

Following two (2) years of satisfactory compliance with stipulations, Respondent may request to work areas which have limited supervision. If such is granted, said employment will be with specified conditions as set forth by the Board. In no event may Respondent engage in unsupervised practice without prior written authorization from the Board or its designee.

18. **Restricted Employment**

Respondent shall not work for a nursing registry, traveling nurse agency, nursing float pool, hospice, home health agency, or temporary employment agency without prior written authorization from the Board or its designee.

19. **Employment - Supervision Restriction**

Respondent shall not be employed as a supervising nurse.

20. **Employment - Access to Drugs (if treatment recommended)**

Respondent shall not administer or have access to controlled substance medications for a minimum of six (6) months of employment, and shall not have access to or administer controlled substance medications until written permission is received from the Board stating this stipulation no longer applies. Respondent shall work in nursing a minimum of six (6) months without this restriction prior to completing the Order.

21. **Employment - Hours of Practice**

Respondent shall not work more than eighty (80) hours in a two (2) week period without prior written authorization from the Board or its designee.

22. **Employment - Notification**

Respondent shall provide all health care employers, collaborative and covering physicians (if CRNP/CNM) and schools of nursing with a copy of this Order and cause each to acknowledge to the Board that a copy of this Order has been provided to them. Said notification

shall be received by the Board no later than ten (10) days after the effective date of this Order or within ten (10) days of Respondent's employment or advanced practice approval or entry into school and must be on the Board-provided form.

23. **Employment - Change in Status**

Respondent shall not accept or change employment without prior written notification to the Board. Said notification must include the name and number of the person who will be Respondent's supervisor.

24. **Employment - Evaluation of Performance**

Respondent shall cause the employer to provide to the Board, on a Board-approved form, a written evaluation of Respondent's nursing performance. Such reports are due quarterly, according to schedule. The receipt of an unfavorable report may be considered to be a violation of this Order. If Respondent is not employed as a nurse, Respondent is required to inform the Board of employment status in the monthly self-report.

25. **Not Employed in Nursing**

In order to complete the terms of this Order, the Respondent must have been employed as a practicing nurse for a minimum period of eighteen (18) months if chemical dependency treatment is recommended. If treatment is not recommended, Respondent must be employed as a practicing nurse for a minimum of twelve (12) months. During periods of employment in fields other than nursing, Respondent is not relieved from compliance with all other terms and conditions of this Order.

26. **Alabama Licensure Status**

Respondent must maintain a current license at all times during the period of probation. If for any reason Respondent allows the nursing license to lapse/expire, such may be cause for disciplinary action.

27. **Notification of Board**

If Respondent is arrested by any law enforcement agency or is admitted as a patient to any institution in this state or elsewhere for treatment regarding the abuse of or dependence on any chemical substance, or for treatment for any emotional or psychological disorder, Respondent shall cause the Board to be notified immediately. Respondent also shall immediately report to the Board any relapse as well as any disciplinary action issued by an employer. Should Respondent test positive on any drug screen conducted by an employer, an employee assistance program, court referral program or other entity, the Respondent shall immediately report such to the Board.

28. **Change of Address**

Respondent shall immediately notify the Board, in writing, of any change of address.

29. **Relocation**

The Respondent must notify the Board of pending relocation outside the State of Alabama. If Respondent plans to relocate to another state, Respondent must inform that state's board of nursing as to licensure status and may request the Alabama Board to transfer monitoring to the other state. If monitored by another state, Respondent must successfully complete all requirements of the Board Order of the other jurisdiction in order to fulfill the terms of this Order. Respondent must submit to the Alabama Board a copy of the Order from the other state and official notification of successful completion or unsuccessful termination thereof. The Board retains the right to withdraw approval for out-of-state monitoring if circumstances indicate that such is appropriate.

30. **Personal Interview**

Respondent shall appear in person for interviews at the request of the Board or Board designee.

31. **Obey the Laws**

Respondent shall refrain from violation of any federal, state or local law or rule or Order of the Board. A conviction on any criminal charge pending at the time of the signing of this

Order may result in further disciplinary action. Any arrest subsequent to the signing of this Order may result in further disciplinary action.

32. **Release of Records and Information**

Respondent hereby authorizes the Board of Nursing, to submit information and all records necessary to ensure compliance with the stipulations of this Order and public safety. This includes communication with Respondent's employer (existing and prospective) and members of Respondent's treatment team regarding noncompliance and/or possible relapse. Respondent also agrees to execute all appropriate release of information forms so as to allow all treatment providers, healthcare providers, employers and all other necessary persons to inform the Board, in writing, of Respondent's status and progress.

33. **Violation**

Any deviation from the requirements of this Order without the written consent of the Board shall constitute a violation of this Order and will be cause for disciplinary action.

34. **Subsequent Practice Act Violation**

Should supplemental cause for disciplinary action arise during the period of this Order such is cause for disciplinary action.

35. **Fraudulent Acts During Period of Order**

Submission of fraudulent documents or reports or misrepresentation of facts relating to the terms and conditions stated herein shall constitute a violation of this Order.

36. **Termination of Order**

This Order shall terminate only upon receipt of documents to satisfy all terms and conditions of this Order, including receipt of official court records documenting successful completion of court-ordered probation, pretrial diversionary-type program, drug court, etc., where applicable. This period of probation will not terminate until notification by the Board to Respondent in writing that all terms and conditions have been met and the probation has been completed.

37. **Public Information**

This Order is public information. All disciplinary actions of the Board will be reported to all required data banks.

38. **Effective Date**

The effective date of this Order shall be the documented date of service or attempted service by certified mail or personal service.

39. **Final Order**

This Order is subject to full Board consideration and acceptance before it shall be final.

EXECUTED on this the 12 day of January 2006

Chasity Denise Beene Martin

CHASITY DENISE BEENE MARTIN

APPROVED AND ACCEPTED by the ALABAMA BOARD OF NURSING on this the 24th day of March 2006

N. Genell Lee

N. GENELL LEE, RN, MSN, JD
EXECUTIVE OFFICER
ALABAMA BOARD OF NURSING

Rev 11/04
/tb

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

CHASITY DENISE BEENE

Thursday, October 05 2023 02:33:32 PM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provide his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, an provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing ve they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BEENE, CHASITY DENISE	RN	868604	Inactive	06/15/2023	08/25/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BEENE, CHASITY DENISE	APRN-CNP	868604	Inactive	07/05/2023	08/25/2023	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 08/25/2023
  - Original Issuance Date: 07/05/2023
  - Current Issue Date: 07/05/2023
  - Certification expiration date: 01/06/2025

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BEENE, CHASITY DENISE	RN	868604	Active	08/25/2023	09/24/2024	NO

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
BEENE, CHASITY DENISE	APRN-CNP	868604	Active Prescribing - CII	08/25/2023	09/24/2024	NO

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 09/24/2024
  - Original Issuance Date: 08/25/2023
  - Current Issue Date: 08/25/2023
  - Certification expiration date: 01/06/2025

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist
- **CNM:** Certified Nurse Midwife
- **CRNA:** Certified Registered Nurse Anesthetist

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PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – January 18, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[~~omitted material~~]** is material to be omitted. and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 639.070; NRS 639.0727

A REGULATION relating to pharmacy; The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standard.

CHAPTER 639 - PHARMACISTS AND PHARMACY

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COMPOUNDING AND DISPENSING DRUG PRODUCTS

General Provisions

NAC 639.661 Definitions. (NRS 639.070**,** 639.2807**)** As used in NAC 639.661 to 639.690, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6611 to 639.6677, inclusive, have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94; A by R035-06, 9-18-2008)

NAC 639.6611 "Active ingredient" defined. (NRS 639.070**)** "Active ingredient" means an ingredient added to a compounded drug product which provides the therapeutic effect desired from the compounded drug product. The term does not include an inert ingredient.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6613 "Ante-area" defined. (NRS 639.070**)** "Ante-area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6615 "Barrier isolator cabinet" defined. (NRS 639.070**)** "Barrier isolator cabinet" means a device the

interior of which creates an ISO Class 5 environment and provides an impermeable barrier to outside air at all times while it is being used for compounding purposes. The term includes, without limitation, compounding aseptic isolators and compounding aseptic containment isolators.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6617 "Beyond-use date" defined. (NRS 639.070**)** "Beyond-use date" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6619 "Buffer area" defined. (NRS 639.070**)** "Buffer area" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6621 "Chart order" defined. (NRS 639.070**)** "Chart order" has the meaning ascribed to it in NAC 639.442.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6623 "Component" defined. (NRS 639.070**)** "Component" means an ingredient that is used to compound a drug product, including, without limitation, an ingredient that does not appear on the labeling of the compounded drug product.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6625 "Compound" and "compounding" defined. (NRS 639.070**)**

1. Except as otherwise provided in subsection 2, "compound" and "compounding" mean:

(a) The preparation, mixing or assembling of a drug product of which at least one component is a prescription drug; and

(b) The packaging and labeling incident to the preparation, mixing or assembling of a drug product for the purpose of selling or dispensing the drug product pursuant to a prescription or chart order.

2. The terms "compound" and "compounding" do not include the mixing or reconstituting of a nonsterile drug product that is performed in accordance with:

(a) The directions contained in the labeling of the drug product that have been approved by the Food and Drug Administration and provided by the manufacturer of the drug product; or

(b) Any other directions provided by the manufacturer of the drug product that are consistent with the labeling of the drug product that have been approved by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6627 "Compounding aseptic containment isolator" defined. (NRS 639.070**)** "Compounding aseptic containment isolator" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6629 "Compounding aseptic isolator" defined. (NRS 639.070**)** "Compounding aseptic isolator" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.663 "Cytotoxic" defined. (NRS 639.070**,** 639.2807**)** "Cytotoxic" means having the capability of killing living cells.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6631 "Drug product" defined. (NRS 639.070**)** "Drug product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the Food and Drug Administration.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6633 "Gloved fingertip sampling" defined. (NRS 639.070**)** "Gloved fingertip sampling" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6635 "Hazardous drug" defined. (NRS 639.070**)** "Hazardous drug" means:

1. A compounded drug product in which one or more of the components of the compounded drug product produce one or more of the following characteristics in humans or animals:
   (a) Carcinogenicity;
   (b) Teratogenicity or other developmental toxicity;
   (c) Reproductive toxicity;
   (d) Organ toxicity at low doses; or
   (e) Genotoxicity; or
2. A compounded drug product in which the structure and toxicity profiles of the compounded drug product mimic an existing drug product which has components that produce one or more of the characteristics set forth in subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.6637 "High-risk sterile compounded drug product" defined. (**NRS 639.070**)** "High-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67067.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6639 "Immediate-use sterile compounded drug product" defined. (NRS 639.070**)** "Immediate-use sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67073.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6641 "ISO Class 5" defined. (NRS 639.070**)** "ISO Class 5" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 100 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6643 "ISO Class 7" defined. (NRS 639.070**)** "ISO Class 7" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 352,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 10,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6645 "ISO Class 8" defined. (NRS 639.070**)** "ISO Class 8" means the classification of an atmospheric environment that is made by the International Organization for Standardization based on an adaptation of Federal Standard 209E, as adopted by reference in paragraph (a) of subsection 1 of NAC 639.670, in which the atmospheric environment contains:

1. Less than 3,520,000 particles that are 0.5 micron or larger in diameter per cubic meter of air; or
2. Less than 100,000 particles that are 0.5 micron or larger in diameter per cubic foot of air.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.6647 "Low-risk sterile compounded drug product" defined. (**NRS 639.070**)** "Low-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67061.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

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NAC 639.6649 "Media fill test" defined. (NRS 639.070**)** "Media fill test" has the meaning ascribed to it in chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.665 "Medical facility" defined. (NRS 639.070, 639.2807**)** "Medical facility" has the meaning ascribed to it in NRS 449.0151.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

~~**NAC 639.6655 "Medium-risk sterile compounded drug product" defined. (**NRS 639.070**)** "Medium-risk sterile compounded drug product" means a sterile compounded drug product which is compounded by a pharmacist or a pharmaceutical technician and which satisfies the requirements set forth in NAC 639.67065.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.6665 "Nonsterile compounded drug product" defined. (NRS 639.070**)** "Nonsterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is not required to be sterile as described in NAC 639.6677.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.667 "Nursing personnel" defined. (NRS 639.070, 639.2807**)** "Nursing personnel" means an employee of:

1. A medical facility who is licensed pursuant to chapter 632 of NRS;
2. A nursing pool as defined in NRS 449.0153; or
3. An agency to provide nursing in the home as defined in NRS 449.0015.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.6673 "Parenteral nutrition" defined. (NRS 639.070**)** "Parenteral nutrition" means nutrients provided intravenously.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6677 "Sterile compounded drug product" defined. (NRS 639.070**)** "Sterile compounded drug product" means a drug product the preparation and dispensing of which require compounding and which is required to be sterile by either the provisions of chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, or the provisions of NAC 639.661 to 639.690, inclusive.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.670 Adoption of certain publications by reference; revision of publication after adoption. (NRS 639.070, 639.2807**)**

1. The Board hereby adopts by reference the following, all licensees must adhere to these standards when compounding:

~~(a) Federal Standard 209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones," as revised on September 11, 1992, by the Institute of Environmental Sciences. A copy of this publication may be obtained free of charge at the Internet address **http://www.set3.com/papers/209e.pdf**.~~

~~(b) NSF International Standard 49, "Class II (Laminar Flow) Biosafety Cabinetry," NSF/ANSI 49-2007, 2007 edition. A copy of this standard~~ may ~~be obtained from Techstreet, 3916 Ranchero Drive, Ann Arbor, Michigan 48108, or at the Internet address **http://www.techstreet.com/**, for the price of $160.~~ Clean room standards set by International Organization for Standardization (ISO), 1214 Verbier, Geneva, Switzerland.

~~(c)~~ *(a)United States Pharmacopeia - National Formulary*, 20~~08~~23 edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address **http://www.usp.org/products/**, ~~for the price of $755~~.

~~(d)~~ (b)The *Food Chemicals Codex*, ~~6~~ 13th edition, published by the United States Pharmacopeial Convention. A copy of this publication may be obtained from the United States Pharmacopeial Convention, Customer Service Department, 12601 Twinbrook Parkway, Rockville, Maryland 20852, or at the Internet address **http://www.usp.org/products/**, ~~for the price of $495.~~

~~(e) *Reagent Chemicals: Specifications and Procedures*, 10th edition, published by the American Chemical Society. A copy of this publication may be obtained from the Oxford University Press, 2001 Evans Road, Cary, North Carolina 27513, or at the Internet address **http://www.oup-usa.org**, for the price of $274.50~~.

~~(f)~~ (c)Appendix A of *Publication No. ~~2004-165~~2016-161*, "Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings," published by the National Institute for Occupational Safety and Health. A copy of this publication may be obtained free of charge by telephone at (800) 232-4636 or at the Internet address **http://www.cdc.gov/niosh/docs/~~2004-165~~2016-161/**.

2. The Board will periodically review the standards and publications adopted by reference pursuant to paragraphs (b) to (f), inclusive, of subsection 1 and determine within 120 days after the review whether any change made to those standards or publications is appropriate for application in this State. If the Board does not disapprove a change to an adopted standard or publication within 120 days after the review, the change is deemed to be approved by the Board.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

Standards for Compounding and Dispensing Generally

NAC 639.6701 Inspection of materials and equipment; recordkeeping. (NRS 639.070**)**

1. A pharmacy or pharmacist engaged in the practice of compounding drug products shall:

(a) Inspect and either approve or reject, without limitation, each component, container, closure, label and other material used in the process of compounding each drug product;

(b) Ensure the proper use, cleanliness and maintenance of any equipment used in the process of compounding each drug product; and

(c) Prepare the records required to be prepared pursuant to NAC 639.661 to 639.690, inclusive, concerning the compounding of each drug product to ensure that an error has not occurred in the process of compounding each drug product.

2. A pharmacy or pharmacist engaged in the practice of compounding drug products may not allow any food or drink to be stored or consumed in or at an area or room in the pharmacy that is designated for compounding.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67013 Competency and proficiency of certain pharmaceutical personnel. (NRS 639.070**)**

1. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall ensure that each pharmacist and pharmaceutical technician engaged in the practice of compounding drug products:

(a) Is competent and proficient in compounding the drug products that the pharmacist or pharmaceutical technician will be authorized and expected to compound;

(b) Complies with the provisions of NAC 639.661 to 639.690, inclusive, concerning the drug products which the pharmacist or pharmaceutical technician compounds and the compounded drug products which the pharmacist or pharmaceutical technician dispenses at the pharmacy; and

(c) Receives, on an ongoing basis, sufficient training to maintain that competency and proficiency.

2. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products shall evaluate the competency and proficiency of a pharmacist and pharmaceutical technician:

(a) If the pharmacist or pharmaceutical technician is newly hired or is newly assigned to compound drug products, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound drug products; and

(b) If the pharmacist or pharmaceutical technician will be assigned to compound drug products that involve a higher level of risk than the drug products which the pharmacist or pharmaceutical technician had previously been trained to compound, before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound those drug products.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67015 Establishment of policies and procedures. (NRS 639.070**)**

1. A pharmacy engaged in the practice of compounding drug products shall establish and maintain written policies and procedures for compounding drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

(a) Policies and procedures for:

(1) The processes used by the pharmacy to compound drug products;

(2) The equipment used by the pharmacy to compound drug products;

(3) Ensuring that the actual weights and measures of each component are within plus or minus 5 percent of the theoretical weights and measures required for the drug products compounded by the pharmacy;

(4) Tracking, recalling and destroying the drug products compounded by the pharmacy, which must include a

requirement that the pharmacy ensure that all drug products which could have been compounded with a particular component be located, recalled and destroyed; and

(5) Identifying the drug products or components of drug products that will be considered hazardous drugs.

(b) Control procedures for monitoring each final compounded drug product and validating the compounding processes that may be responsible for causing variability in the final compounded drug product.

(c) Control procedures to ensure that:

(1) Each component is accurately weighed, measured or subdivided, as appropriate;

(2) Any variation in the actual yield of a drug product compounded by the pharmacy is within plus or minus 10 percent of the theoretical yield of the compounded drug product; and

(3) If a component is transferred from its original storage container to a new storage container, the new storage container is labeled with the date of the transfer and information that is sufficient to trace the contents of the new container to the original storage container.

2. A member of the staff of the Board may require a pharmacy engaged in the practice of compounding drug products to provide a sample of a drug product that is being compounded at the time of the request and any records related to that compounded drug product for purposes of testing the compounded drug product for compliance with the provisions of NAC 639.661 to 639.690, inclusive. The Board will share the costs of testing such a sample equally with the pharmacy.

3. If a sample tested pursuant to subsection 2 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will notify the pharmacy of the failure to comply and the pharmacy must:

(a) Provide to the Board a written plan for remediating or addressing the noncompliance; and

(b) If requested by a member of the staff of the Board, provide an additional sample of the compounded drug product for testing. The costs of a test conducted pursuant to this paragraph must be paid solely by the pharmacy.

4. If the sample provided to the Board pursuant to paragraph (b) of subsection 3 does not comply with the provisions of NAC 639.661 to 639.690, inclusive, the Board will take such action as it deems necessary to correct the noncompliance or to prevent further noncompliance, including, without limitation:

(a) Suspending the license of the pharmacy pursuant to NRS 639.210;

(b) Suspending the ability of the pharmacy to compound certain drug products; and

(c) Requiring the pharmacy to perform any other remedial or protective measures the Board deems necessary to correct the noncompliance or to prevent further noncompliance.

NAC 639.67017 Use of automated compounding devices. (NRS 639.070**)**

1. A pharmacy may use an automated compounding device to:

(a) Assist with the compounding of a drug product; or

(b) Produce a final compounded drug product.

2. If a pharmacy uses an automated compounding device as described in subsection 1, the pharmacy shall establish and maintain written policies and procedures, in addition to the policies and procedures established and maintained pursuant to NAC 639.67015, that address:

(a) The qualifications that a pharmacist or a pharmaceutical technician must have to use the automated compounding device;

(b) The routine maintenance and cleaning required to be performed on the automated compounding device which, at a minimum, satisfies the requirements for maintenance and cleaning established by the manufacturer of the automated compounding device; and

(c) The testing required to be performed on the automated compounding device to ensure that the automated compounding device is measuring and dispensing the components of the compounded drug product and manufacturing the final compounded drug product within tolerances of not more than plus or minus 5 percent.

3. If a pharmacy uses an automated compounding device to assist with the compounding of a drug product for parenteral nutrition, the pharmacy shall establish safe maximum limits for each additive that may be used in compounding such a drug product. The pharmacy shall ensure that:

(a) The automated compounding device will cease compounding the drug product for parenteral nutrition if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order; or

(b) If an automated compounding device cannot be programmed to cease the compounding process as described in paragraph (a):

(1) The automated compounding device is equipped with an audible alarm or some other mechanism that will alert the pharmacist if a maximum limit for an additive has been exceeded; and

(2) The pharmacy has written policies and procedures to prevent the continuation of the compounding process once a maximum limit for an additive has been exceeded until a pharmacist, after consultation with the prescribing

practitioner, makes changes to or validates the correctness of the prescription or chart order.

4. If the pharmacy uses a computerized order entry system in conjunction with the automated compounding device, the pharmacy must ensure that the computerized order entry system will cease processing the order if a maximum limit for an additive will be exceeded until a pharmacist, after consultation with the prescribing practitioner, makes changes to or validates the correctness of the prescription or chart order.

5. A pharmacy shall make and maintain records that evidence compliance by the pharmacy with the policies and procedures required by this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67019 Retention of records. (NRS 639.070**)**

1. Except as otherwise provided in NAC 639.67055, each record required to be made pursuant to NAC 639.661 to 639.690, inclusive, must be:

(a) Maintained by the pharmacy for which the record was made for at least 2 years after the date the record was made; and

(b) Available for inspection and copying by the Board or its representative.

2. Records made and maintained by a pharmacy pursuant to NAC 639.67055 must be available for inspection and copying by the Board or its representative after the 6-month period required by NAC 639.67055 if the pharmacy maintains the records longer than the required 6-month period.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.6702 Records concerning drug products compounded in excess and in bulk quantities. (NRS 639.070**)** For each compounded drug product that is in excess of the amount required by the prescription or chart order and each compounded drug product that is compounded in bulk quantities, the pharmacist who compounded or supervised the compounding of the compounded drug product shall prepare a record, either on paper or in the pharmacy's computer system, that includes, without limitation:

1. The name of the compounded drug product;

2. A list of the components and quantities of components used to compound the drug product, including, without limitation, the manufacturer or supplier of the components used, the lot number of the components used and the expiration dates of the components used;

3. The internal control number assigned to the compounded drug product by the pharmacist or the number of the prescription of the compounded drug product;

4. The beyond-use date of the compounded drug product;

5. The date of preparation of the compounded drug product;

6. The initials of the pharmacist or pharmaceutical technician who compounded the compounded drug product;

7. If the drug product was compounded by a pharmaceutical technician, the initials of the pharmacist who supervised the pharmaceutical technician; and

8. The quantity of the final compounded drug product.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Nonsterile Products

NAC 639.6703 Labeling. (NRS 639.070**)**

1. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall label each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order and any nonsterile compounded drug product that is compounded in bulk quantities. The label must include, without limitation:

(a) The name of the final compounded drug product or the name of each active ingredient present in the nonsterile compounded drug product and, as appropriate, the concentration of each active ingredient in the final compounded drug product;

(b) The internal control number assigned to the compounded drug product by the pharmacist; and

~~(c) The beyond-use date of the compounded drug product.~~

~~2. Except as otherwise provided in subsection 3 or in the published data or data of the manufacturer, or as otherwise determined to be earlier in the judgment of the pharmacist, the latest beyond-use date of a nonsterile compounded drug product is:~~

~~(a) For nonaqueous liquids and solid formations, not later than the expiration date of the active ingredient present in the nonsterile compounded drug product with the earliest expiration date or 6 months after the date on which the nonsterile~~

~~compounded drug product was compounded, whichever is earlier;~~

~~(b) For compounds which contain nonsterile water, not later than 14 days after the date on which the nonsterile compounded drug product was compounded; and~~

~~(c) For compounds other than those listed in paragraph (a) or (b), not later than the intended duration of the therapy or 30 days after the date on which the nonsterile compounded drug product was compounded, whichever is earlier.~~

~~3. Except as otherwise provided in subsection 7 of NRS 639.2801, a pharmacy may use a beyond-use date that is later than the dates described in subsection 2 if the pharmacy can prove by appropriate testing or published data that the nonsterile compounded drug product is safe and effective using the extended beyond-use date.~~

~~4.~~ 2. Each pharmacist engaged in the practice of compounding nonsterile compounded drug products shall ensure that each nonsterile compounded drug product, including, without limitation, any amount of the nonsterile compounded drug product that is in excess of the amount required by the prescription or chart order, and any nonsterile compounded drug product that is compounded in bulk quantities is stored in the pharmacy in a manner that:

(a) Maintains the efficacy of the nonsterile compounded drug product; and

(b) Ensures that the nonsterile compounded drug product remains free from contamination.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.67033 Environmental standards.** (NRS 639.070) A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall:~~

~~1. Designate a specific area of the pharmacy in which nonsterile compounded drug products will be compounded;~~

~~2. Ensure that the area described in subsection 1 has adequate space in which to place, in an orderly manner, the equipment and materials that will be used in the compounding process;~~

~~3. Ensure that the area described in subsection 1 is cleaned using an antiseptic cleaning method before and after any compounding occurs in the area to prevent cross-contamination between the previously compounded drug products and any subsequently compounded drug products;~~

~~4. Ensure that any equipment used to compound a nonsterile compounded drug product is cleaned after the compounding of that drug product is completed to prevent cross-contamination from occurring when the equipment is used in the compounding process of any subsequently compounded drug products;~~

~~5. If the pharmacy compounds both nonsterile compounded drug products and sterile compounded drug products, ensure that none of the equipment which is used to compound nonsterile compounded drug products is used to compound sterile compounded drug products unless the equipment is cleaned and sanitized before the compounding of sterile compounded drug products begins; and~~

~~6. Ensure that any employee of the pharmacy who compounds nonsterile compounded drug products washes his or her hands with soap and water or with an antimicrobial agent before and after compounding nonsterile compounded drug products.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67035 Establishment of policies and procedures. (NRS 639.070) A pharmacy engaged in the practice of compounding nonsterile compounded drug products shall, in addition to the requirements of NAC 639.67015, establish and maintain written policies and procedures for compounding nonsterile compounded drug products to ensure that each final compounded drug product has the identity, strength, quality and purity which the compounded drug product is purported or represented to have. Such policies and procedures must include, without limitation:

~~1.~~ Policies and procedures for:

(a) Making and maintaining records concerning the components used to compound each nonsterile compounded drug product;

(b) The amount of each component used to compound each nonsterile compounded drug product;

(c) The order of each step in the process of compounding each nonsterile compounded drug product; and

(d) Including the information listed in paragraphs (a), (b) and (c) on the original hard copy of the prescription maintained in the written records of the pharmacy or in a computer system that may be accessed to provide information:

(1) For refilling the prescription; or

(2) Requested by the staff of the Board.

~~2.~~ Control procedures for monitoring each final nonsterile compounded drug product and validating the processes for compounding that may be responsible for causing variability in the final nonsterile compounded drug product. Such control procedures must include, without limitation, procedures for evaluating:

(a) Any variation of more than plus or minus 10 percent in the weight of the capsules, tablets or any other solid form of a dosage of the same nonsterile compounded drug product;

(b) The adequacy of mixing to ensure uniformity and homogeneity of each nonsterile compounded drug product;

(c) If applicable, the clarity, completeness and pH of a nonsterile compounded drug product;
(d) If applicable, the even distribution of coloring agents; and
(e) Any variation of more than plus or minus 10 percent in the actual yield of a nonsterile compounded drug product compounded by the pharmacy as compared to the theoretical yield of the nonsterile compounded drug product.
~~3.~~ Control procedures to ensure:
(a) If the final nonsterile compounded drug product is a capsule, that the capsule is properly locked;
(b) If the final nonsterile compounded drug product is a tablet or any other solid form of dosage, that the final compounded drug product is of a uniform size and is intact;
(c) If the final nonsterile compounded drug product is a suppository, that the suppository is properly sealed;
(d) If the final nonsterile compounded drug product is an oral liquid, that, to the extent possible, the liquid is palatable to the patient;
(e) If the final nonsterile compounded drug product is a suspension, that the visible suspended particles are of uniform size and are readily dispersed upon shaking; and
(f) If the final nonsterile compounded drug product is a topical compounded drug product, that the final compounded drug product is smooth and not gritty and has a uniform viscosity unless grittiness is required for a particular therapeutic purpose.
(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.67037 Safety procedures for storage, handling, compounding and disposal; training required. (**~~NRS 639.070~~)~~

~~1. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs shall:~~
~~(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;~~
~~(b) Handle the components of the hazardous drugs with caution by using appropriate gloves while distributing, receiving, stocking, inventorying, and preparing for administering and disposing of the components of a hazardous drug or a final compounded drug product;~~
~~(c) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, face masks, eye protection, double gloves or chemotherapy gloves;~~
~~(d) Dispose of all waste relating to compounding hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and~~
~~(e) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.~~
~~2. A pharmacy engaged in the practice of compounding nonsterile hazardous drugs and dispensing compounded nonsterile hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds nonsterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:~~
~~(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a nonsterile hazardous drug that will be administered or dispensed to a patient; and~~
~~(b) At least once each year thereafter.~~
~~3. The training required pursuant to subsection 2 must, at a minimum, include information concerning:~~
~~(a) Safe manipulation practices that minimize exposure to the hazardous drug and protect employees of the~~

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~~pharmacy from any overt exposure to the hazardous drug;~~
~~(b) Procedures for containment, cleaning and disposal with regard to breaks and spills; and~~
~~(c) Treatment of employees of the pharmacy with regard to exposure by contact and inhalation.~~
~~4. The pharmacy shall make and keep a record of any training given pursuant to subsection 2.~~
~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.XXX Flavoring a prescription.

1. A pharmacist may add flavoring to an oral solution at the request of a patient or their legal guardian.
   a. The pharmacist must make the record contemporaneous with the completion of the mixture, including but not limited to ingredients of the product, and
   b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug, and
   c. The beyond use date of the product is assigned in accordance with USP 795 standards.

NAC 639.XXX Mixing of ready to use products.

1. A pharmacist may mix components of commercially manufactured ready to use FDA approved products.
   a. The pharmacist must make the record contemporaneous with the completion of the mixture, including but not limited to ingredients of the product, and
   b. The beyond use date of the product is assigned in accordance with USP 795 standards, and
   c. The pharmacist must follow all FDA approved mixing instructions.

Standards for Compounding and Dispensing Sterile Products

~~**NAC 639.6705 Environmental standards.** (NRS 639.070)~~

~~1. Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall provide an ISO Class 5 environment.~~

~~2. If a pharmacy uses a laminar airflow hood as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy:~~

~~(a) Shall ensure that the laminar airflow hood is located within a room with a buffer area that maintains an ISO Class 7 environment under normal conditions of use.~~

~~(b) Shall maintain an ante-area or space in close proximity to any entrance to the room containing the laminar airflow hood that maintains an ISO Class 8 environment under normal conditions of use.~~

~~(c) Shall ensure that the room that contains the laminar airflow hood maintains a constant temperature and humidity that:~~

~~(1) Ensures the safety and efficacy of the compounded drug products, components and equipment; and~~

~~(2) Provides an environment in which the employees of the pharmacy can work comfortably for the duration of the compounding that will be conducted in the room.~~

~~(d) Shall require each employee of the pharmacy who enters the buffer area containing the laminar airflow hood to:~~

~~(1) Remove all jewelry from his or her hands and arms;~~

~~(2) Perform sanitizing scrubbing; and~~

~~(3) Wear fresh protective clothing, including, without limitation, gowns, shoe covers or dedicated shoes, and hair covers, in the ante-area or space in close proximity to an entrance to the room and to remove all such items of protective clothing whenever the employee leaves the room. A gown may be used more than once within a 12-hour period if it is removed in the ante-area and is stored in the ante-area until it is used again.~~

~~(e) Shall require an employee to wear nonpowdered gloves and a face mask and beard cover, as applicable, before the employee enters the buffer area.~~

~~(f) Shall ensure, to the extent practicable, that all items located in or brought into the room containing the laminar airflow hood have nonporous, smooth, impermeable surfaces that:~~

~~(1) Can withstand being cleaned repeatedly with a disinfectant; and~~

~~(2) Do not shed particles which may become airborne in the room.~~

~~(g) Must have floors, walls and ceilings in the room containing the laminar airflow hood that are made of materials that can withstand being cleaned and disinfected repeatedly with solutions and products.~~

~~(h) Shall ensure, before any compounding can occur within the laminar airflow hood, that the laminar airflow hood is~~

used according to the manufacturer's directions with regard to starting and using the laminar airflow hood in a manner ~~which ensures that the interior of the laminar airflow hood creates and maintains an ISO Class 5 environment.~~

(i) ~~Shall ensure that:~~

~~(1) The ISO Class 5 environment is cleaned:~~

~~(I) At the beginning of each work shift;~~

~~(II) Before the compounding of each batch preparation begins;~~

~~(III) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;~~

~~(IV) After there has been a spill within the ISO Class 5 environment; and~~

~~(V) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.~~

~~(2) The counters and easily cleanable work surfaces in close proximity to the laminar airflow hood and in, or in close proximity to, the buffer area are cleaned at least once each day in which the ISO Class 5 environment is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.~~

~~(3) The floors are cleaned at least once each day in which the ISO Class 5 environment is used and whenever the floors may require cleaning as a result of its use throughout the working day.~~

~~(4) The walls, ceilings, storage, shelving and other surfaces that are not easily cleaned are cleaned at least once each month.~~

~~3. If a pharmacy uses a barrier isolator cabinet that maintains an ISO Class 5 environment at all times when it is in use as its ISO Class 5 environment within which to compound sterile compounded drug products, the pharmacy shall ensure that:~~

~~(a) The barrier isolator cabinet is placed in the pharmacy at a location where: (1)~~

~~The compounding may occur without interruption or inconvenience; and~~

~~(2) The barrier isolator cabinet will not be compromised by its proximity to air vents, doorways or other pharmacy fixtures or equipment.~~

~~(b) Before any compounding may occur within the barrier isolator cabinet, the barrier isolator cabinet is used according to the manufacturer's directions with regard to starting and using the barrier isolator cabinet in a manner which ensures that the interior of the barrier isolator cabinet creates and maintains an ISO Class 5 environment.~~

~~(c) The barrier isolator cabinet is cleaned:~~

~~(1) At the beginning of each work shift;~~

~~(2) Before the compounding of each batch preparation begins;~~

~~(3) At least every 30 minutes after the compounding of a sterile compounded drug product has begun during a period of continuous compounding activity;~~

~~(4) After there has been a spill within the ISO Class 5 environment; and~~

~~(5) Whenever it is known or suspected that surface contamination exists as a result of a breach in procedure.~~

~~(d) The counters and easily cleanable work surfaces in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever a counter or surface may require cleaning as a result of its use throughout the working day.~~

~~(e) The floors in close proximity to the barrier isolator cabinet are cleaned at least once each day in which the barrier isolator cabinet is used and whenever the floors may require cleaning as a result of its use throughout the working day.~~

~~4. A barrier isolator cabinet that cannot maintain an ISO Class 5 environment at all times when it is being used shall be deemed a laminar airflow hood for purposes of satisfying the requirements of this section.~~

~~5. As used in this section, "batch preparation" means the compounding of multiple units of sterile compounded drug products, not for immediate use, in a single process by the same person.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

~~NAC 639.67051 Air quality testing and certification.~~ ~~(NRS 639.070)~~

~~1. Except as otherwise provided in NAC 639.67059, a pharmacy engaged in the practice of compounding sterile compounded drug products shall test the air in each of its controlled environments to ensure that the environments attain the air quality required by the provisions of NAC 639.661 to 639.690, inclusive, for an ISO Class 5, ISO Class 7 or ISO Class 8 environment, as applicable.~~

2. ~~The air quality testing required by subsection 1 must be performed randomly with regard to:~~

~~(a) The time of day the air samples are collected;~~

~~(b) The staff who is on duty when the samples are gathered; and~~

~~(c) The locations within the pharmacy from which the samples are collected.~~

~~3. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have its ISO Class 5 environment certified pursuant to subsection 4:~~

~~(a) At least twice each year; and~~
~~(b) Before compounding a sterile compounded drug product after:~~
~~(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;~~
~~(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;~~
~~(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or~~
~~(4) The laminar airflow hood or barrier isolator cabinet is repaired.~~
~~4. The certification required by subsection 3 must be completed by a person who is independent of the pharmacy requesting the certification and who is capable of certifying that the ISO Class 5 environment can satisfy and maintain the minimum requirements set forth in NAC 639.6641 for air quality under normal conditions of use.~~
~~5. A pharmacy engaged in the practice of compounding sterile compounded drug products shall have each of its ISO Class 7 and ISO Class 8 environments tested or certified pursuant to subsection 7 for particulates:~~
~~(a) At least twice each year; and~~
~~(b) Before compounding a sterile compounded drug product after:~~
~~(1) A substantial change or renovation is made in the room that contains the laminar airflow hood or barrier isolator cabinet;~~
~~(2) Sizeable equipment is placed in the room that contains the laminar airflow hood or barrier isolator cabinet;~~
~~(3) The laminar airflow hood or barrier isolator cabinet is moved from the location at which the laminar airflow hood or barrier isolator cabinet was most recently tested; or~~
~~(4) A laminar airflow hood or barrier isolator cabinet is added to or removed from the room that contains the laminar airflow hood or barrier isolator cabinet.~~
~~6. The air quality testing required by subsection 5 must be performed randomly with regard to:~~
~~(a) The time of day the air samples are collected;~~
~~(b) The staff who are on duty when the samples are gathered; and~~
~~(c) The locations within the pharmacy from which the samples are collected.~~
~~7. The testing or certification required by subsection 5 must be completed by the pharmacy or by a person who is independent of the pharmacy requesting the certification and who is capable of testing or certifying that the ISO Class 7 or ISO Class 8 environment can satisfy and maintain the minimum requirements set forth in NAC 639.6643 and 639.6645, respectively, for air quality under normal conditions of use.~~
~~8. If the pharmacy performs the testing or certification required by subsection 5, the testing or certification process of the pharmacy must be validated semiannually by the managing pharmacist.~~
~~9. If any of the results of the air quality testing or certification required by this section exceed the tolerances set forth in NAC 639.6641, 639.6643 and 639.6645, for the particular controlled environment, the pharmacy shall take whatever action is necessary to remediate the deficiency and retest the environment until the environment produces results within the tolerances for the particular controlled environment.~~
~~10. The pharmacy shall make and maintain records concerning the air quality testing and certification and any corrections and retesting that were conducted pursuant to this section.~~
~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67053 Tests for competency and proficiency of certain pharmaceutical personnel. (NRS 639.070)

~~1. Except as otherwise provided in subsections 4 and 5, a~~ 1. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products ~~shall require each pharmacist and pharmaceutical technician who compounds sterile compounded drug products to pass a media fill test which~~ must ~~be conducted~~ compound in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, ~~and which must be commensurate to the highest level of risk of compounding sterile compounded drug products that the pharmacist or pharmaceutical technician will be authorized by the pharmacy to perform:~~
~~(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile compounded drug product that will be administered or dispensed to a patient;~~
~~(b) At least once each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound low-risk sterile compounded drug products or medium-risk sterile compounded drug products; and~~
~~(c) At least twice each year thereafter if the pharmacy authorizes the pharmacist or pharmaceutical technician to compound high-risk sterile compounded drug products.~~
~~2. A pharmacy engaged in the practice of compounding and dispensing sterile compounded drug products shall ensure the competency and proficiency of each pharmacist and pharmaceutical technician who compounds at the highest~~

~~level of risk of compounding sterile compounded drug products the pharmacist or pharmaceutical technician is authorized by the pharmacy to perform by:~~

~~(a) Requiring the pharmacist or pharmaceutical technician to provide a sample for a gloved fingertip sampling which must be conducted in the manner provided by chapter 797 of the *United States Pharmacopeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670;~~

~~(b) Testing a sample taken from a surface cleaned by the pharmacist or pharmaceutical technician to determine sterility;~~

~~(c) Ensuring the pharmacist or pharmaceutical technician receives, on an ongoing basis, sufficient training to maintain that competency and proficiency through attending in-house training programs or continuing education courses;~~

~~(d) Observing the pharmacist or pharmaceutical technician as he or she compounds sterile compounded drug products; or~~

~~(e) Correcting any error and initiating remedial measures for a pharmacist or pharmaceutical technician to take after an error has been noted with a sterile compounded drug product that was made or verified by the pharmacist or pharmaceutical technician.~~

2. A pharmacy shall make and maintain records concerning all the actions listed in subsection 1 ~~2~~ which the pharmacy takes to ensure the competency and proficiency of each pharmacist and pharmaceutical technician who is authorized by the pharmacy to compound sterile compounded drug products.

~~3. A sterile compounded drug product that is compounded by a pharmacist or pharmaceutical technician who has not passed the media fill test required by paragraph (a) of subsection 1 may be dispensed and administered to a patient if:~~

~~a. The managing pharmacist of the pharmacy determines that it is appropriate to dispense and administer the sterile compounded drug product; and~~

~~b. The entire compounding process was personally witnessed by a pharmacist or pharmaceutical technician who passed the media fill test.~~

~~4. A pharmacy is not required to make a pharmacist or pharmaceutical technician pass a media fill test pursuant to paragraph (a) of subsection 1 if the pharmacist or pharmaceutical technician provides evidence of passing a media fill test:~~

~~a. Within the immediately preceding 9 months if the pharmacist or pharmaceutical technician will compound low- risk sterile compounded drug products and medium-risk sterile compounded products; or~~

~~b. Within the immediately preceding 5 months if the pharmacist or pharmaceutical technician will compound high-risk sterile compounded drug products.~~

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67055 Record verifying accuracy required to be made. (NRS 639.070**)**

1. For all sterile compounded drug products compounded by a pharmacy, other than an institutional pharmacy, and for all sterile drug products for parenteral nutrition and sterile antineoplastic drug products compounded by an institutional pharmacy, a pharmacist shall make a record verifying the accuracy of each sterile compounded drug product that the pharmacist:

(a) Compounded;

(b) Verified the accuracy of after it was compounded by a pharmaceutical technician; or

(c) Dispensed for administration to a patient in a medical facility.

2. A pharmacist required to make a record pursuant to subsection 1 shall:

(a) Make the record contemporaneous with the completion of the compounding, verifying or dispensing of the sterile compounded drug product;

(b) Include in the record information identifying the patient for which the sterile compounded drug product was made and the date the sterile compounded drug product was compounded; and

(c) Initial the record if it is a written record or enter an initial or other identifying mark onto the record if the record is made in a computerized system.

3. A pharmacy for which a record was made pursuant to subsection 1 shall ensure that the record is maintained for at least 6 months after the date the sterile compounded drug product was compounded, verified or dispensed.

4. If a sterile compounded drug product is compounded by a pharmaceutical technician, the pharmaceutical technician shall make a record of the compounding in the same manner as a pharmacist is required to make a record pursuant to this section.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67057 Procedures following breach of seal of single-dose and multi-dose containers. (NRS 639.070**)**

~~1. If, in the course of compounding a drug product, the seal of a single-dose container, including, without limitation, a bag, bottle, syringe or vial of a sterile drug product, is breached, the time and date of the breach must be~~

~~marked upon the container and the contents of the container may be used:~~

~~(a) Within 1 hour after the breach of the seal if:~~

~~(1) The breach occurred in an environment with an air quality that is worse than ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that is worse than ISO Class 7;~~

~~(b) Within 6 hours after the breach of the seal if:~~

~~(1) The breach of the seal occurred and the contents of the container were used in an environment with an air quality that satisfies or exceeds ISO Class 5; and~~

~~(2) The container is subsequently stored in an environment with an air quality that satisfies or exceeds ISO Class 7; or~~

(c) ~~Within 24 hours after the breach of the seal if the breach occurred in an environment with an air quality that satisfies or exceeds ISO Class 5 and the container remains in an environment with an air quality that satisfies or exceeds ISO Class 5.~~

~~2.~~ (1) If, in the course of compounding a drug product, the seal of a multi-dose container is breached:

(a) The container must be stored according to the requirements of the manufacturer; and

(b) The contents of the container may be used within 28 days after the breach of the seal occurred.

~~3.~~ (2) Any drug product that is not used within the periods set forth in subsection 1 ~~or 2~~ may not be used and must be destroyed.

~~4.~~ (3) If the seal of a single-use ampule is breached or the entire seal has been removed from a multi-use vial and the contents are not used at the time of the breach, the contents may not be used and must be destroyed.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~**NAC 639.67059 Exemptions for certain institutional pharmacies.** (NRS 639.070) The Board may, upon application and for good cause shown, waive or modify any requirement set forth in NAC 639.6705 and 639.67051 for an institutional pharmacy engaged in the practice of compounding drug products if the institutional pharmacy serves an institution that:~~

~~1. Has less than 100 beds licensed for providing acute care; and~~

~~2. Is located in a county:~~

~~(a) Whose population is less than 100,000; or~~

~~(b) Whose population is 100,000 or more if the hospital is designated as a rural hospital by the Nevada Office of Rural Health within the University of Nevada School of Medicine.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

~~**NAC 639.67061 Low-risk sterile compounding: Process and storage.** (NRS 639.070)~~

~~1. A compounded drug product is a low-risk sterile compounded drug product if:~~

~~(a) The compounded drug product is required to be sterile for its effective administration;~~

~~(b) The sterile compounded drug product is at a low risk of contamination; and~~

~~(c) One or more of the following conditions are present:~~

~~(1) The compounding process involves aseptic manipulations that are performed entirely within an environment with an air quality of at least ISO Class 5 and uses only sterile ingredients, products, components and devices;~~

~~(2) The compounding process involves only transferring, measuring and mixing manipulations and uses not more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;~~

~~(3) The manipulations needed to compound the drug product are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile drug products and containers for storage and dispensing;~~

~~(4) The final compounded drug product contains a volume of 15 milliliters or less of a radiopharmaceutical and has an expiration time of 18 hours or less per dosage unit, including, without limitation, a dosage unit of a radiopharmaceutical prepared from an eluate by using a molybdenum-99technetiym-99m generator; or~~

~~(5) The final compounded drug product contains commercially manufactured cyclotron radiopharmaceuticals which contain preservatives and which have expiration times of 72 hours or less.~~

~~2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a low-risk sterile compounded drug product must not exceed:~~

~~(a) Forty-eight hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);~~

~~(b) Fourteen days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or~~

~~(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.~~

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67063 Low-risk sterile compounding: Radiopharmaceutical drug products. (NRS 639.070) If a nuclear pharmacy compounds radiopharmaceutical drug products, the nuclear pharmacy shall ensure that, in addition to satisfying the requirements of NAC 639.5828:

1. The radiopharmaceutical compounded drug products are compounded in a vertical laminar airflow hood or Class II type B2 biological safety cabinet that is located in an environment with an air quality of ISO Class 8 or higher;

2. Only shielded vials, syringes and other devices and containers specifically manufactured for use with radiopharmaceutical components are used in the compounding process;

3. Each employee of the nuclear pharmacy who will compound radiopharmaceutical drug products is trained and knowledgeable with regard to compounding, handling, cleaning and any special techniques used with radiopharmaceutical drug products; and

4. Any special equipment or device that is used to compound radiopharmaceutical products, including, without limitation, a molybdenum-99technetiym-99m generator, is used, stored and maintained according to the directions of the manufacturer of the equipment or device.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67065 Medium-risk sterile compounding: Process and storage. (NRS 639.070) 1. A compounded drug product is a medium-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is compounded using aseptic techniques pursuant to one of the conditions listed in NAC 639.67061 as a condition for a low-risk sterile compounded drug product; and

(c) One or more of the following conditions are present:

(1) Individual or small doses of sterile drug products are combined or pooled to prepare the final compounded drug product that will be administered to multiple patients or to one patient multiple times;

(2) The compounding process includes complex aseptic manipulations other than a single-volumetransfer;

(3) The compounding process uses more than three commercially manufactured sterile drug products or other entries of a sterile drug product into one container, including, without limitation, a bag or vial, to make the final compounded drug product;

(4) The final compounded drug product does not contain broad-spectrum bacteriostatic substances and will be administered over a period which exceeds 24 hours; or

(5) The compounding process requires an unusually long duration, as determined by the managing pharmacist, including, without limitation, the period required to complete dissolution or homogeneous mixing.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a medium-risk sterile compounded drug product must not exceed:

(a) Thirty hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Nine days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67067 High-risk sterile compounding: Process and storage. (NRS 639.070)

1. A compounded drug product is a high-risk sterile compounded drug product if:

(a) The compounded drug product is required to be sterile for its effective administration;

(b) The sterile compounded drug product is contaminated with or at a high risk of becoming contaminated with infectious microorganisms; and

(c) One or more of the following conditions are present:

(1) One or more of the ingredients or devices used in the compounding process are nonsterile; or

(2) One or more of the ingredients or devices used in the compounding process were sterile but were exposed or are suspected of having been exposed for more than 1 hour to an air quality inferior to an ISO Class 5 environment.

2. Unless sterility testing or potency limitations allow for a different period, the period of storage before administration of a high-risk sterile compounded product must not exceed:

(a) Twenty-four hours at a controlled room temperature that is at least 20 degrees Celsius (68 degrees Fahrenheit) but not more than 25 degrees Celsius (77 degrees Fahrenheit);

(b) Three days at a temperature that is at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees

Celsius (46 degrees Fahrenheit); or

(c) Forty-five days in a solid frozen state that is -10 degrees Celsius (14 degrees Fahrenheit) or colder.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67069 High-risk sterile compounding: Sterilization. (NRS 639.070)

1. Except as otherwise provided in subsection 5, a pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products shall ensure that each such compounded drug product is sterilized through filtration, by using steam in an autoclave or by dry heat. Except as otherwise provided in subsection 5, a pharmacist engaged in the practice of compounding high-risk sterile compounded drug products shall choose the method of sterilization that ensures the strength, purity, quality and packaging integrity of the final compounded drug product.

2. If a pharmacy sterilizes high-risk sterile compounded drug products using the filtration method, the pharmacy shall:

(a) Use commercially available sterile filters that are:

(1) Pyrogen-free and have a nominal porosity of 0.2 micron or 0.22 micron; and

(2) Certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas* (*Pseudomonas*) *diminuta* on each square centimeter of upstream filter surface area under conditions similar to the conditions of sterilization of the high-risk compounded drug products;

(b) Ensure that the filters used have sufficient capacity to permit the sterilization process to be completed rapidly and without compromising the sterility of the filtration process; and

(c) Subject the filtration units to the manufacturer's recommended integrity testing, including, without limitation, the bubble point test, after the filtration of the high-risk sterile compounded drug products is completed.

3. If a pharmacy sterilizes high-risk sterile compounded drug products using steam in an autoclave, the pharmacy shall:

(a) Expose each high-risk sterile compounded drug product to steam at 121 degrees Celsius (250 degrees Fahrenheit) under a pressure of 15 pounds per square inch for the duration of the sterilization process;

(b) Before starting the sterilization process, ensure that plastic, glass and metal devices are wrapped in low particle shedding paper or fabric or sealed in envelopes that prevent microbial penetration after the sterilization of the high-risk sterile compounded drug products is completed;

(c) Ensure that the solutions that will be used to fill the vials which will be steam sterilized are passed through a filter having a porosity of not more than 1.2 microns to remove particulate matter immediately before filling those vials; and

(d) Verify the mass of the container that will be sterilized using steam in an autoclave to ensure that the container will be sterile after the period of exposure in that autoclave.

4. If a pharmacy sterilizes high-risk sterile compounded drug products using dry heat, the pharmacy shall ensure that:

(a) The heated air is filtered and evenly distributed by a blower throughout the chamber or oven used for the sterilization process; and

(b) The chamber or oven used for the sterilization process is equipped with accurate temperature controls and a timer.

5. A pharmacy may only use dry heat as a method of sterilization for a high-risk sterile compounded drug product if the final high-risk sterile compounded drug product would be damaged by moisture or is impermeable to moisture.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67071 High-risk sterile compounding: Testing of certain drug products. (NRS 639.070)

1. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for injection into the vascular system or central nervous system shall test a quantity of the high-risk sterile compounded drug product for:

(a) Sterility using a membrane filtration method or an equivalent method, as determined by the Board, before any of the compounded drug product may be administered or dispensed to a patient; and

(b) Excessive bacterial endotoxins using an appropriate test, as determined by the Board, for the particular product at issue before any of the compounded drug product may be administered or dispensed to a patient.

2. A pharmacy engaged in the practice of compounding and dispensing high-risk sterile compounded drug products for inhalation or ophthalmic use shall test a quantity of each such high-risk sterile compounded drug product for sterility.

3. The provisions of subsections 1 and 2 apply only to high-risk sterile compounded drug products:

(a) Compounded in groups of more than 25 identical individual single-dose packages;

(b) Compounded in multiple-dose vials for administration to multiple patients; or

(c) That will be exposed for a period of more than:

~~(1) Twelve hours to temperatures of at least 2 degrees Celsius (36 degrees Fahrenheit) but not more than 8 degrees Celsius (46 degrees Fahrenheit); or~~

~~(2) Six hours to temperatures exceeding 8 degrees Celsius (46 degrees Fahrenheit) before the compounded drug product is sterilized.~~

~~4. If any high-risk sterile compounded drug product tested pursuant to this section tests positive for antimicrobial growth or endotoxin production, the high-risk sterile compounded drug product must not be administered or dispensed to a patient.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67073 Immediate-use sterile compounding: Preparation and labeling. (NRS 639.070**)** ~~1.~~

~~A sterile compounded drug product is an immediate-use sterile compounded drug product if:~~

~~(a) The compounded drug product is intended only for the purpose of emergency care or immediate care of a patient;~~

~~(b) The compounding of the drug product occurs in an environment other than an ISO Class 5 environment and the compounding process consists of simple aseptic measuring and transfer manipulations performed with not more than six sterile nonhazardous commercial drug products and diagnostic radiopharmaceutical drug products, excluding infusion solutions or diluents;~~

~~(c) The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour unless a period longer than 1 hour is required for the reconstitution of the compounded drug product;~~

~~(d) During compounding and before the administration of the compounded drug product, no part of the drug product or critical surfaces and ingredients of the drug product is directly exposed to contact contamination, including, without limitation, human touch, cosmetic flakes or particulates, blood or other bodily substances of a person or nonsterile inanimate sources; and~~

(e) ~~Except as otherwise provided in paragraph (c), the administration of the compounded drug product begins not later than 1 hour after the start of the preparation of the compounded drug product and the compounded drug product is fully administered as soon as practicable but not longer than 24 hours after the administration of the compounded drug product began or the compounded drug product is disposed of promptly and safely.~~

~~2.~~ (1) If an immediate-use sterile compounded drug product is not immediately administered by direct injection into a patient by the person who compounded it, the compounded drug product must bear a label which includes, without limitation:

(a) The name and, if the patient has an identification number, the identification number of the patient;

(b) The name and amount of each ingredient of the compounded drug product;

(c) The initials of the person who compounded the compounded drug product; and

(d) The exact date and time of expiration of the compounded drug product.

~~3.~~ (2) An immediate-use sterile compounded drug product must not be stored for later use. (Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

~~NAC 639.67075 Immediate-use sterile compounding: Compounding standards. (~~NRS 639.070**~~)~~**

~~1. An immediate-use sterile compounded drug product that contains three or less commercial sterile drug products that will be stored more than 1 hour before administration is begun must comply with all compounding standards applicable to low-risk sterile compounded drug products.~~

~~2. An immediate-use sterile compounded drug product which contains more than three commercial sterile drug products or which requires complex manipulations or complex preparation must comply with all compounding standards applicable to medium-risk sterile compounded drug products.~~

~~3. An immediate-use sterile compounded drug product that contains one or more nonsterile ingredients or components must comply with all compounding standards applicable to high-risk sterile compounded drug products.~~

~~(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)~~

NAC 639.67077 Sterile hazardous drugs: Safety procedures for storage, handling, compounding and disposal. (NRS 639.070**)**

1. A pharmacy engaged in the practice of compounding sterile hazardous drugs shall:

(a) Store the components of the hazardous drugs separately from all the other inventory at the pharmacy and in such a manner and location as to minimize the contamination of other drugs in and employees of the pharmacy;

(b) Handle the components of the hazardous drugs with caution by using appropriate gloves during preparation, handling and disposal of the components of the hazardous drug or final compounded drug product;

(c) Compound the hazardous drugs pursuant to the requirements set forth in NAC 639.661 to 639.690, inclusive, and applicable to the risk level of the compounded hazardous drugs;

(d) Ensure that an employee of the pharmacy involved with compounding hazardous drugs wears personal protective equipment, including, without limitation, gowns, gloves, face masks, hair covers, shoe covers or dedicated shoes, and, if the hazardous drugs contain one or more antineoplastic agents or it is recommended by the drug manufacturer, double gloves or chemotherapy gloves;

(e) Dispose of all waste relating to the compounding of the hazardous drugs in a manner that complies with any applicable state, federal and local laws and regulations; and

(f) Ensure that any employees of the pharmacy who are known to the pharmacy to be at special risk with regard to the properties of the hazardous drugs are limited from exposure to those drugs.

2. A pharmacy shall ensure that the process of compounding sterile hazardous drugs is performed only in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator if one or more of the components of the hazardous drug are:

(a) An antineoplastic drug;

(b) A radiopharmaceutical drug; or

(c) A drug whose manufacturer has recommended that the drug only be compounded in an ISO Class 5 environment in either a biological safety cabinet or a compounding aseptic containment isolator.

3. The biological safety cabinet or compounding aseptic containment isolator described in paragraph (c) of subsection 2 must be vented to outside air during the compounding process through the use of high efficiency particulate air filtration if one or more of the components of the compounded hazardous drug are antineoplastic drugs.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

NAC 639.67079 Sterile hazardous drugs: Required training for certain pharmaceutical personnel. (NRS 639.070**)**

1. A pharmacy engaged in the practice of compounding sterile hazardous drugs and dispensing sterile compounded hazardous drugs shall require each pharmacist and pharmaceutical technician who compounds sterile hazardous drugs to be trained in the storage, handling, compounding, safety procedures and disposal of such compounded drugs:

(a) Before the pharmacy authorizes the pharmacist or pharmaceutical technician to compound a sterile hazardous drug that will be administered or dispensed to a patient; and

(b) At least once each year thereafter.

2. The training required pursuant to subsection 1 must include, at a minimum, information concerning:

(a) Safe aseptic manipulation practices;

(b) Negative pressure techniques for use with a biological safety cabinet, compounding aseptic containment isolator or compounding aseptic isolator;

(c) The correct use of a vial transfer device in a closed system;

(d) Procedures for containment, cleaning and disposal with regard to breaks and spills; and

(e) Treatment of employees of the pharmacy with regard to contact and inhalation exposure.

3. The pharmacy shall make and keep a record of any training given pursuant to subsection 1.

(Added to NAC by Bd. of Pharmacy by R035-06, eff. 9-18-2008)

Standards for Compounding and Dispensing Parenteral Solutions

NAC 639.672 Reference materials required to be located in or immediately available to pharmacy. (NRS 639.070**,** 639.2807**)** Any pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy. The reference materials must include information on:

1. All drugs and chemicals used in services related to parenteral therapy; and

2. The activities involved in parenteral therapy, including manufacturing, dispensing, distribution and counseling.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87)

NAC 639.680 Labeling. (NRS 639.070**,** 639.2807**)**

1. In addition to any other requirements for labeling, the label of any parenteral solution must include:

(a) The name and concentrations of all ingredients contained in the parenteral solution, including the primary solution; and

(b) Instructions for storage and handling.

2. The label of a parenteral solution which is used by a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility must include the telephone number of the pharmacy that furnished the parenteral solution.

3. Any cytotoxic agent must bear a special label which states:
(a) "Chemotherapy - Dispose of Properly;" or
(b) "Biohazard - Dispose of Properly."

4. As used in this section, "biohazard" means a biological agent that may be hazardous to persons or the environment.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.682 Record for each patient. (NRS 639.070**,** 639.2807**)**

1. A pharmacy engaged in the practice of compounding and dispensing parenteral solutions shall have on the premises or readily accessible:
(a) A record for each patient being treated with parenteral therapy;
(b) A summary of the most recent hospitalization of the patient or the patient's medical history; and
(c) Any notes taken by the pharmacist concerning the progress of the patient which document any contact with the patient or the practitioner concerning the parenteral therapy.

2. In addition to any other requirements for keeping records, the following records must be maintained in the pharmacy:
(a) Records concerning any prescriptions and medical supplies furnished to the patient.
(b) Information relevant to the patient's parenteral therapy, including, but not limited to:
(1) The patient's name, age, height, weight, sex and address and the telephone number of the location where the patient is receiving parenteral therapy;
(2) The diagnosis of the patient; and
(3) The patient's history of medication, including his or her current regimen concerning diet and medication and any allergies to drugs or food.
(c) Data of a laboratory relevant to the parenteral therapy.
(d) If the patient is using a parenteral solution in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located in that medical facility, records indicating that the care of the patient is coordinated by the pharmacy, practitioner and nursing personnel before the administration of the parenteral solution, including:
(1) Documentation of all orders for medication, laboratory tests or other treatment related to the medication of the patient.
(2) Documentation of all orders given by a practitioner which were communicated to nursing personnel by a pharmacist.
(3) Documentation that a total assessment of the patient has been performed.
(4) Documentation that a plan for the parenteral therapy of the patient has been developed by the pharmacy. The plan must include:
(I) The identification of any problem related to a drug that is administered to the patient; and
(II) Any suggested solution for that problem and the monitoring of the results of the therapy.

3. As used in this section, "total assessment" means an evaluation of the circumstances of the administration of parenteral therapy to a patient in the patient's home, in a facility for the dependent or in a medical facility which does not furnish the parenteral solution from a pharmacy located within that medical facility that includes a review of:
(a) The state of the disease of the patient;
(b) The regimen of medication of the patient;
(c) The medical history of the patient;
(d) Any therapies other than parenteral therapy administered to the patient; and
(e) If the patient is using the parenteral solution in the patient's home, the ability of the patient to receive parenteral therapy in his or her home.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

NAC 639.683 Delivery, storage and recordation of delivery. (NRS 639.070**,** 639.2807**)** A managing pharmacist shall ensure that:

1. A sterile parenteral solution is furnished to a patient in a container which is capable of maintaining the appropriate temperature for the storage of the sterile parenteral solution;

2. A patient is advised of the appropriate conditions for the storage and disposal of the sterile parenteral solution; and

3. The delivery of a controlled substance listed in schedule II, as set forth in NAC 453.520, is documented and a receipt which indicates that the patient received that controlled substance is included with the records maintained at the pharmacy.

(Added to NAC by Bd. of Pharmacy, eff. 7-7-94)

NAC 639.686 Written policies and procedures for disposal of infectious materials and materials containing cytotoxic residues. (NRS 639.070**,** 639.2807**)** In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy providing parenteral solutions shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues. The procedures must contain methods for the cleanup of spills and must be in conformance with the regulations of the local health authority. The pharmacy shall ensure the return of infectious materials and materials containing cytotoxic residues to the pharmacy or shall inform the provider of care of the procedures for the proper destruction of such materials.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A by R035-06, 9-18-2008)

NAC 639.688 Written policies and procedures regarding provision of services related to parenteral therapy. (NRS 639.070**,** 639.2807**)** In addition to the requirements of NAC 639.67015 and 639.67017, any pharmacy, other than an institutional pharmacy, engaged in the practice ofcompounding and dispensing parenteral solutions shall have written policies and procedures relating to:

1. The qualifications and training of employees of the pharmacy to compound and dispense parenteral solutions.
2. A determination of the necessity for administering the medication a patient requires in a parenteral form.
3. The compounding and control of the quality of parenteral solutions.
4. The distribution and delivery of parenteral solutions.
5. The clinical monitoring of parenteral therapy.
6. The availability of a practitioner, pharmacist and nursing personnel during the administration of parenteral therapy to a patient.
7. The availability of products and equipment which are necessary during the administration of parenteral therapy to a patient.
8. The communication of orders among the practitioner, pharmacist and nursing personnel for a patient who requires parenteral therapy.
9. The coordination of the care of a patient who requires parenteral therapy by the pharmacist, practitioner and nursing personnel, including documentation of participation in any conference relating to the care of that patient.
10. The education of a patient relating to:

(a) The self-administration of a parenteral solution;
(b) The proper maintenance and storage of a parenteral solution; and
(c) The operation of devices used to administer parenteral solutions.

11. The cleaning and maintenance of equipment used to administer a parenteral solution furnished to a patient by the pharmacy.
12. The provision of services relating to parenteral therapy furnished by the pharmacy in an emergency.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94; R035-06, 9-18-2008)

NAC 639.690 Pharmacist: Consultation with patient; proper training in safe handling, compounding and therapy related to parenteral solutions. (NRS 639.070**,** 639.2807**)**

1. Any pharmacy furnishing parenteral solutions shall ensure that a pharmacist is available 24 hours a day for consultation with the patient and the patient's primary provider of care concerning the proper use of any parenterals and related supplies furnished by the pharmacy.
2. The managing pharmacist shall ensure that all pharmacists engaging in compounding parenteral solutions have the proper training in the safe handling, compounding and therapy related to parenteral solutions, including cytotoxic agents.

(Added to NAC by Bd. of Pharmacy, eff. 8-14-87; A 7-7-94)

OUTSOURCING FACILITIES

NAC 639.691 Definitions. (NRS 639.070**,** 639.100**)** As used in NAC 639.691 to 639.6916, inclusive, unless the context otherwise requires, the words and terms defined in NAC 639.6911, 639.6912 and 639.6913 have the meanings ascribed to them in those sections.

(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6911 "Compounding" defined. (NRS 639.070**,** 639.100**)** "Compounding" includes, without limitation, the

combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug.
(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6912 "Outsourcing facility" defined. (NRS 639.070**,** 639.100**)** "Outsourcing facility" means a facility at one geographic location or address that:
1. Is engaged in the compounding of sterile drugs; and
2. Has registered with the Secretary of Health and Human Services as an outsourcing facility pursuant to 21 U.S.C. § 353b.
(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6913 "Sterile drug" defined. (NRS 639.070**,** 639.100**)** "Sterile drug" means a drug that is:
1. Intended for parenteral administration;
2. An ophthalmic or oral inhalation drug in aqueous format; or
3. Required to be sterile pursuant to the provisions of federal law or the provisions of NAC 639.661 to 639.690, inclusive.
(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.6915 Duties of facility. (NRS 639.070**,** 639.100**)** An outsourcing facility that is engaged in the compounding of sterile drugs in this State or for shipment into this State shall:
1. Obtain a license from the Board as a manufacturer in accordance with NRS 639.100 and 639.233 by submitting an application on a form prescribed by the Board;
2. Comply with the provisions of NAC 639.609 to 639.619, inclusive; and
3. Comply with all the requirements of 21 U.S.C. § 353b.
(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015; A by R025-21, 4-11-2022)

NAC 639.6916 When licensure as pharmacy required. (NRS 639.070**,** 639.100**)**
1. Except as otherwise provided in subsection 2, an outsourcing facility is not required to be licensed as a pharmacy.
2. An outsourcing facility may dispense dangerous drugs or controlled substances for identified individual patients pursuant to a prescription only if the outsourcing facility is licensed by the Board as a pharmacy in accordance with NRS 639.230 or 639.2328, as applicable.
(Added to NAC by Bd. of Pharmacy by R003-15, eff. 12-21-2015)

NAC 639.757 Preparation and sale of compounded drugs by registrants ~~pharmacy or pharmacist~~: License as manufacturer not required under certain circumstances; unsafe or ineffective drug; restrictions on sale. (NRS 639.070**)**
1. A ~~pharmacy or pharmacist~~ pharmacy, pharmacist, or practitioners is not required to obtain a license as a manufacturer to compound drugs if:
(a) The compounded drugs are prepared in a quantity that is:
(1) Necessary to fill a prescription or chart order; or
(2) Reasonably necessary to fill future prescriptions or chart orders based upon the previous history of practitioners and patients who regularly use the pharmacy or dispensing practitioner;
(b) The compounded drugs are not sold or otherwise provided by the ~~pharmacy or pharmacist~~ registrant to any person other than the ultimate user of the drugs, the agent of the ultimate user of the drugs and; ~~or a practitioner who will be administering the drugs to a patient~~;
(c) The compounded drugs are dispensed pursuant to a prescription or chart order;
~~(d)~~ 2. A pharmacy, pharmacist or practitioner may only compound drugs products using substances that: ~~Except as otherwise provided in paragraph (e) and subsection 2, the active ingredients used to compound the drugs:~~

(a) Comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding;

(b) Are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or

(c) Appear on FDA's list of bulk drug substances that can be used in compounding (the 503A) if such a

monograph does not exist and the substance is not a component of an FDA-approved drug product.

3. An outsourcing facility is not required to obtain a license as a manufacturer to compound drugs if,

(a) Compounding drug products that appear on FDA's drug shortage list at the time of compounding, distribution, and dispensing; or

(b) Compounding drug products that appear on FDA's list of bulk drug substances for which there is a clinical need (the 503B bulks list).

~~(1) Are authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto; and~~

~~(d) Except as otherwise provided in subsection 2, for an active ingredient used to compound the drugs that does not have a monograph in the *United States Pharmacopoeia - National Formulary*, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670, the active ingredient is:~~

~~(1) Prepared by a manufacturer or distributed by a distributor registered with the Food and Drug Administration; (2) Accompanied by a certificate of analysis provided by the manufacturer or distributor of the ingredient; and (3) Prepared to a grade that, at a minimum, satisfies the requirements set forth in:~~

~~(I) The *Food Chemicals Codex*, as adopted by reference in paragraph (d) of subsection 1 of NAC 639.670; or~~

~~(II) *Reagent Chemicals: Specifications and Procedures*, as adopted by reference in paragraph (e) of subsection 1 of NAC 639.670, if the active ingredient is a certified analytical reagent, is for use in high pressure liquid chromatography, is for use in spectrophotometric applications or is a primary standard grade for use in standard solutions for analytical purposes.~~

~~4. In compounding a drug product, a pharmacy or pharmacist may use an active ingredient that does not satisfy the requirements of paragraphs (d) and (e) of subsection 1 if the pharmacy or pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient. A pharmacy shall make and maintain a record of the means that the pharmacy relied upon in determining that an ingredient was pure and safe pursuant to this subsection.~~

~~5.~~ 4. Except as otherwise provided in this subsection, a pharmacy or pharmacist shall not compound a drug that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective. A pharmacy or pharmacist may compound a drug for veterinary use that has been withdrawn or removed from the market because the drug was found to be unsafe or ineffective for use in humans if the drug remains available for veterinary use.

~~6. A pharmacy shall not sell or otherwise provide a compounded drug to a retail pharmacy or a practitioner, except that a pharmacy may sell or otherwise provide a compounded drug to:~~

~~(a) A practitioner who will be administering the drug to a patient; or~~

~~(b) A practitioner or another pharmacy if the compounded drug is:~~

~~(1) A highly concentrated drug product that is not commercially available; or~~

~~(2) Needed to fill a particular prescription or chart order in the possession of the receiving pharmacy at the time the receiving pharmacy orders the compounded drug from the compounding pharmacy.~~

~~7. The quantity of a compounded drug that is sold or otherwise provided to a practitioner or pharmacy pursuant to subsection 4 must not exceed the amount necessary for the practitioner or pharmacy to serve the present needs of the patients of the practitioner or pharmacy.~~

(Added to NAC by Bd. of Pharmacy by R032-02, eff. 5-31-2002; A by R035-06, 9-18-2008)

DRAFT

15B

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – March 7, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[~~omitted material~~]** is material to be omitted. and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: § 1, NRS 639.070, Senate Bill 336

A REGULATION relating to pharmacy; establishing the registration requirements for certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 of NRS, to order, prescribe, possess and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth; and providing other matters properly relating thereto.

Section 1. Chapter 639 of NAC is hereby amended by adding thereto a new section to read as follows:

1. ***The application of a certified registered nurse anesthetist for a certificate of registration to order, prescribe, possess, and administer controlled substances, poisons, dangerous drugs, and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth, must include:***
    a. ***The name, address, social security number and telephone number of the applicant; and***
    b. ***Any other information requested by the Board.***
2. ***Each certified registered nurse anesthetist who applies for a certificate of registration may be required by the Board to appear personally before the Board for a determination and an assignment of the specific authority to be granted to the certified registered nurse anesthetist.***

3. *Any certificate of registration issued pursuant to subsection 1 and 2 is a revocable privilege and no holder of such a certificate acquires any vested right therein or thereunder.*
4. *A certified registered nurse anesthetist shall notify the Board in writing of a change in location of the practice of the certified registered nurse anesthetist not later than 10 days after the change occurs.*

Section 2. NAC 639.900 is hereby amended as follows:

The Board may deny the application of an advanced practice registered nurse *or a certified registered nurse anesthetist* for a certificate of registration or suspend or revoke his or her certificate of registration if the advanced practice registered nurse *or certified registered nurse anesthetist*:

1. Is not of good moral character;
2. Is guilty of habitual intemperance;
3. Becomes or is under the influence of liquor, any depressant drug or a controlled substance while on duty, unless the drug or substance has been taken pursuant to a physician's prescription;
4. Is guilty of unprofessional conduct or conduct contrary to the public interest;
5. Is addicted to the use of any controlled substance;
6. Has been convicted of a violation of any federal law or law of this or any other state relating to controlled substances;
7. Has been convicted of a felony or other crime involving moral turpitude, dishonesty or corruption;
8. Has willfully made to the Board or its authorized representative any false written statement which is material to the administration or enforcement of any provision of chapter 453, 454 or 639 of NRS;
9. Has obtained a registration by filing any application, record or affidavit, or any information in support thereof, which is false or fraudulent;
10. Has violated any provision of the Federal Food, Drug, and Cosmetic Act or any other state or federal law or regulation relating to prescription drugs;
11. Has failed to renew his or her registration by failing to pay the renewal fee;
12. Has failed to maintain the security of his or her drug supply;

13. Has supplied patients with prescriptions that are presigned in blank; or

14. Has violated any provision of chapter 453, 454, 585 or 639 of NRS or any regulation pertaining to the practice of pharmacy, controlled substances, dangerous drugs or devices.

Section 3. NAC 639.220 is hereby amended as follows:

1. The Board hereby adopts the following schedule of fees:

For the examination of an applicant for registration as a pharmacist.....	Actual cost of the examination
For the investigation or registration of an applicant as a registered pharmacist.....	$200
For the investigation, examination or registration of an applicant as a registered pharmacist by reciprocity.....	200
For the investigation or issuance of an original license to conduct a retail pharmacy.....	500
For the biennial renewal of a license to conduct a retail pharmacy.....	500
For the investigation or issuance of an original license to conduct an institutional pharmacy.....	500
For the biennial renewal of a license to conduct an institutional pharmacy	500
For the investigation or issuance of an original license to conduct a pharmacy in a correctional institution.....	500
For the biennial renewal of a license to conduct a pharmacy in a correctional institution.....	500
For the investigation or issuance of an original license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS.....	500
For the biennial renewal of a license to conduct a pharmacy in a recovery center or ambulatory surgical center licensed pursuant to chapter 449 of NRS.....	500

For the issuance of an original or duplicate certificate of registration as a registered pharmacist	50
For the biennial renewal of registration as a registered pharmacist	200
For the reinstatement of a lapsed registration (in addition to the fees for renewal for the period of lapse)	100
For the initial registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training	50
For the biennial renewal of registration of a pharmaceutical technician, pharmaceutical technician in training, dispensing technician or dispensing technician in training	50
For the investigation or registration of an intern pharmacist	40
For the biennial renewal of registration as an intern pharmacist	40
For the investigation or registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances	80
For the biennial renewal of registration of an advanced practice registered nurse or a physician assistant to prescribe drugs that are not controlled substances	80
For authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances	200
For the biennial renewal of authorization of a physician, advanced practice registered nurse, physician assistant, euthanasia technician, facility for treatment with narcotics, researcher, instructional user or any other authorized person, except a practitioner who is a medical intern or resident physician, to prescribe or possess controlled substances	200
For authorization of certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 of	***200***

NRS, to order, prescribe, possess and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.....	
For biennial renewal of authorization of certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 of NRS, to order, prescribe, possess and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.....	*200*
For the biennial renewal of authorization of a practitioner who is a medical intern or resident physician to prescribe or possess controlled substances.....	80
For the investigation or issuance of an original license to engage in business as an authorized warehouse or medical products provider.....	500
For the biennial renewal of a license to engage in business as an authorized warehouse or medical products provider.....	500
For the investigation or issuance of an original license to a manufacturer or wholesaler.....	1,000
For the biennial renewal of a license for a manufacturer or wholesaler.....	1,000
For the reissuance of a license issued to a pharmacy, when no change of ownership is involved, but the license must be reissued because of a change in the information required thereon.....	50
For authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense	300

controlled substances or dangerous drugs, or both, for human consumption.....	
For the biennial renewal of authorization of a practitioner, other than a licensed veterinarian, to dispense controlled substances or dangerous drugs, or both, for human consumption for each location where the practitioner will dispense controlled substances or dangerous drugs, or both, for human consumption.....	300
For authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption....	150
For the biennial renewal of authorization of a licensed veterinarian to dispense controlled substances or dangerous drugs, or both, not for human consumption.....	150
For the investigation or issuance of an original license for an automated drug dispensing system.....	500
For the biennial renewal of a license for an automated drug dispensing system.....	500
For the investigation or issuance of an original license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....	250
For the biennial renewal of a license to a pharmacy authorizing the use of a mechanical device to furnish drugs and medications for administration to patients at a medical facility.....	250

2. The penalty for failure to pay the renewal fee for any license, permit or certificate within the statutory period, as provided in subsection 6 of NRS 639.170, is 50 percent of the renewal fee for each period of delinquency in addition to the renewal fee for each period of delinquency.

3. Any person who has been registered as a pharmacist in this State for at least 50 years is not required to pay the fee for the biennial renewal of a certificate of registration as a registered pharmacist.

4. The provisions of this section concerning the fee for the biennial renewal of the authorization to dispense controlled substances or dangerous drugs do not apply to an advanced practice registered nurse who is required to pay a fee pursuant to NAC 639.870.

5. A practitioner employed by or serving as an independent contractor of a health center:

(a) Which is a federally-qualified health center that provides health care primarily to medically underserved persons in a community; and

(b) Which is not a medical facility as defined in NRS 449.0151,

Ê is not required to pay a fee to the Board for a change of address or for an additional address at which the practitioner dispenses drugs.

6. A practitioner who is exempt from the payment of a fee pursuant to subsection 5 shall notify the Board in writing of each change of address or additional address, or both.

7. In addition to any other fees paid by an applicant for a certificate, license or permit issued pursuant to chapter 639 of NRS, the Board may require that the applicant pay the actual costs of inspection incurred by the Board.

15C

Proposed Regulation of the Nevada State Board of Pharmacy

Workshop March 7, 2024

Explanation – Language in ***blue italics*** is new; language in ***red text*** [~~*omitted material*~~] is language to be omitted, and language in ***green text*** indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: NRS 453.146; NRS 453.221; NRS 639.070

A REGULATION relating to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.

NAC 453.510 is hereby amended to read as follows:

1. Schedule I consists of the drugs and other substances listed in this section by whatever official, common, usual, chemical or trade name designated

2. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including, without limitation, their isomers, esters, ethers, salts and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation:

Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide);

Acetylmethadol;

Acryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide) (some trade or other names: acryloylfentanyl);

Allylprodine;

Alpha' -methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-phenylbutanamide);

Alphacetylmethadol (except levo-alphacetylmethadol, commonly referred to as levo-alpha-

acetylmethadol, levomethadyl acetate or “LAAM”);

Alphameprodine;

Alphamethadol;

Alphamethylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine);

Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

Benzethidine;

Betacetylmethdol;

Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxy-3-methylfentanyl (other name: N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

Beta-hydroxythiofentanyl (trade or other names: N-[1-[2-hydroxy-2-(thiophen-2-yl)ethyl]piperidin-4-yl]-N-phenylpropionamide; N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide);

Betameprodine;

Betamethadol;

Betaprodine;

Butyryl fentanyl (trade or other names: N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide; N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Clonitazene;

Cyclopentylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide);

Cyclopropylfentanyl(N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide);

Dextromoramide;

Diampromide;

2',5'-dimethoxyfentanyl (N *-(1-(2,5 dimethoxyphenethyl)piperidin-4-yl)* N*-phenylpropionamide);*

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambuten;

Dioxaphetyl butyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Eutylone (bk-EBDB, 1-(1,3-Benzodioxol-5-yl)-2-(ethylamino)butan-1-one, b-keto-ethylbenzodioxolylbutanamine);

Fentanyl carbamate (Ethyl-(1-phenethylpiperidin-4-yl)(phenyl)carbamate);

Fluoro furanyl fentanyl;

Fluoroacryl fentanyl;

Fluorobutyryl fentanyl;

Fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]propanamide);

Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Furanyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide);

3-furanyl fentanyl (N *-(1-phenethylpiperidin-4-yl)-* N *-phenylfuran-3-carboxamide);*

Furethidine;

Hydroxypethidine;

Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide);

Isovaleryl fentanyl (3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);

Isotonitazene;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Meta -fluorofentanyl (N -(3-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)propionamide);

Meta -fluoroisobutyryl fentanyl (N -(3-fluorophenyl)- N -(1-phenethylpiperidin-4-yl) isobutyramide);

Methoxyacetyl fentanyl***;***

Methyl acetyl fentanyl;

Methyl methoxyacetyl fentanyl (some trade or other names: 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl));

Methylfentanyl;

Methylthiofentanyl;

Morpheridine;

MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

Noracymethadol;

Norlevorphanol;

Normethadone;

N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluro 2'-fluorofentanyl);

Norpipanone;

Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;

Ortho -fluorofuranyl fentanyl (N -(2-fluorophenyl)- N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);

Para-fluorobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide);

Para -methoxyfuranyl fentanyl (N -(4-methoxyphenyl)- N -(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

Para -methylcyclopropyl fentanyl (N -(4-methylphenyl)- N -(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Phenyl fentanyl (some trade or other names: benzoyl fentanyl);

Phenylpropanoyl fentanyl;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);

Tianeptine;

Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

Thiofuranyl fentanyl (some trade or other names: thiophene fentanyl);

Tilidine;

Trimeperidine; or

Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide).

3. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Acetorphine;

Acetyl fentanyl;

Acetyldihydrocodeine;

Benzylmorphine;

Codeine methylbromide;

Codeine-N-Oxide;

Cyprenorphine;

Desomorphine;

Dihydromorphine;

Drotebanol;

Etorphine (except hydrochloride salt);

Heroin;

Hydromorphinol;

Methyldesorphine;

Methyldihydromorphine;

Morphine methylbromide;

Morphine methylsulfonate;

Morphine-N-Oxide;

Myrophine;

Nicocodeine;

Nicomorphine;

Normorphine;

Pholcodine; or

Thebacon.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

ADB–BUTINACA (some trade or other names: N -(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1 H -indazole-3-carboxamide

ADB-4en-PINACA (some trade or other names: N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1H-indazole-3-carboxamide)

Adinazolam (some trade or other names: 8-chloro-1-((dimethylamino)methyl)-6-phenyl-4H-s-triazlo(4,3-a)(1,4)benzodiazepine; adinazolamum; Deracyn);

Alpha-ethyltryptamine (some trade or other names: ET, Trip);

Alpha-methyltryptamine (some trade or other names: AMT);

Alpha -PiHP (some trade or other names: 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one)

Bromazolam (some trade or other name: 8-bromo-1-methyl-6-phenyl H[1,2,4]triazolo[4,3a][1,4]benzodiazepine; XLI-268);

1,4-Butanediol (some trade or other names: 1,4-butyleneglycol, dihydroxybutane, tetramethylene glycol, butane 1,4-diol, SomatoPro, Soma Solutions, Zen);

~~3~~ bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-bromo-2,5-dimethoxyphenethylamine (some trade or other names: Nexus, 2C-B);

1-Butyl-3-(1-naphthoyl)indole-7173 (some trade or other names: JWH-073);

2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-C);

4-(2-chlorophenyl)-2-ethyl-9-methyl-6H-thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine (some trade or other names: Etizolam);

Clonazolam (some trade or other names: 6-(2-chlorophenyl)-1-methyl-8-nitro-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; clonitrazolam);

1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (some trade or other names: SR-18; BTM-8; RCS-8);

CUMYL-PEGACLONE (some trade or other names: SGT-151; 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one; 2,5-dihydro-2-(1-methyl-1-

phenylethyl)-5-pentyl-1H-pyrido[4,3-b]indol-1-one)

Diclazepam (some trade or other names: 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-1-methyl-2H-1,4-benzodiazepine-2-one; 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2H-benzo[e][1,4]diazepin-2-one; 2'-chlorodiazepam; Chlorodiazepam; Ro 5-3448);

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA);

2,5-dimethoxy-4-ethylamphet-amine (some trade or other names: DOET);

2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (some trade or other names: 2C-E);

2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (some trade or other names: 2C-D);

2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (some trade or other names: 2C-N);

2,5-Dimethoxy-N-(2-methoxybenzyl) phenethylamine (NBOMe) and any derivative thereof (some trade or other names: 2C-X-NBOMe; N-benzylated phenethylamines; N- o-methoxybenzyl analogs; NBOMe; 25H-NBOMe; 25B-NBOMe; 25C-NBOMe; 25D-NBOMe; 25E-NBOMe; 25I-NBOMe; 25N-NBOMe; 25P-NBOMe; 25T2-NBOMe; 25T4-NBOMe; 25T7-NBOMe);

2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (some trade or other names: 2C-P);

2,5-dimethoxy-4-(n)-propylthiophenethylamine (some trade or other names: 2C-T-7);

2-(2,5-Dimethoxyphenyl)ethanamine (some trade or other names: 2C-H);

3-[(2-Dimethylamino)ethyl]-1H-indol-4-yl acetate (some trade or other names: 4-acetoxy- N, N-dimethyltryptamine;4-AcO-DMT; psilacetin; O-acetylpsilocin; 4-acetoxy-DMT);

5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7297 (some trade or other names: CP-47,497);

5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol-7298 (some trade or other

names: cannabicyclohexanol; CP-47,497 C8 homologue);

Ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-EDMB-PINACA);

4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone (some trade or other names: (4- ethyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone; JWH-210);

2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-2);

4F-MDMB-BUTICA (some trade or other names: 4F-MDMB-BICA; Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(4-fluorobutyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, methyl)

5F-EDMB-PICA (some trade or other names: 5F-EDMB-2201; Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate; N-[[1-(5-fluoropentyl)-1H-indol-3-yl]carbonyl]-3-methyl-L-valine, ethyl ester)

Flualprazolam (some trade or other names: 8-chloro-6-(2-fluorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine; 8-chloro-6-(2-fluoro-phenyl)-1-methyl-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; 2'-fluoro alprazolam; ortho-fluoro alprazolam);

Flubromazepam (some trade or other names: 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-Bromo-5-(2-fluorophenyl)-1H-benzo[e][1,4]diazepin- 2(3H)-one; 7-bromo-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one);

Flubromazolam (some trade or other names: 8-bromo-6-(2-fluorophenyl)-1-methyl-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine);

Flunitrazolam (some trade or other names: 6-(2-fluorophenyl)-1-methyl-8-nitro-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine);

(1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: FUB-144);

2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (Some trade or other names: FUB-AMB; MMB-FUBINACA);

[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (some trade or other names: THJ-2201; 5-fluoro THJ 018; AM2201 indazole analog; fluorpentyl JWH-018 indazole);

[1-(5-fluoropentyl)-1H-indol-3-yl]-1-naphthalenyl-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(1-naphthoyl)indole; AM-2201);

[1-(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophyenyl)-methanone (some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole; AM-694);

(1-(5-fluoropentyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other names: XLR-11);

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (some trade or other names: 5F-CUMYL-PINACA; SGT-25);

1-(5-fluoropentyl)-N-(tricyclo[3.3.1.13,7]dec-1-yl)-1H-indazole-3-carboxamide (some trade or other names: N-((3s,5s,7s)-adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide; APINACA 5-fluoropentyl analog; 5F-AKB48; 5-Fluoro-AKB48; 5F-APINACA; 5-Fluoro-APINACA;

1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-(5-fluoropentyl)-1H-indole-3-carboxylic acid 8-quinolinyl ester; 5-Fluoro-PB-22; 5F-PB-22);

Flutoprazepam (some trade or other names: 7-chloro-1-(cyclopropylmethyl)-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one);

2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (some trade or other names: 2C-I);

2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (some trade or other names: 2C-T-4);

1-hexyl-3-(1-naphthoyl)indole (some trade or other names: JWH-019);

MDMB-4en-PINACA (some trade or other names: Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1H-indazole-3-carboxamido)butanoate)

Meclonazepam (some trade or other names: (3S)-5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one; Ro 11-3128);

Methoxetamine (some trade or other names: MXE; 2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)

3–MMC (some trade or other names: 3-methylmethcathinone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one)

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-methylphenethylamine; para-methoxyamphetamine; PMA);

(4-methoxy-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-081);

5-methoxy-3,4-methylenedioxyamphetamine (some trade or other names: MMDA);

5-methoxy-N, N-diisopropyltryptamine (some trade or other names: 5-meO-DIPT);

4-methyl-2,5-dimethoxyamphetamine (some trade or other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; “DOM”; “STP”);

(4-methyl-1-naphthalenyl)(1-pentyl-1H-indol-3-yl)-methanone (some trade or other names: JWH-122);

Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (some trade

or other names: 5F-ADB; 5F-MDMB-PINACA);

Methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (some trade or other names: 5F-MDMB-PICA);

Methylenedioxyamphetamine (some trade or other names: MDA);

Methylenedioxymethamphetamine (MDMA);

Methylenedioxy-N-ethylamphetamine (commonly referred to as N-ethyl-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-ethyl MDA, MDE, MDEA);

1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole-7200 (some trade or other names: JWH-200);

MMB-FUBICA ester (some trade or other names: Methyl 2-(1-(4-fluorobenzyl)-1H-indole-3-carboxamido)-3-methyl butanoate; N-[[1-[(4-fluorophenyl)methyl]-1H-indol-3-yl]carbonyl]-L-valine, methyl ester

N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (some trade or other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-fluorobenzyl);

N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (some trade or other names: 1-pentyl-N-tricyclo[3.3.1.13,7]dec-1-yl-1H-indazole-3-carboxamide; APINACA; AKB48);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other names: ADB-CHMINACA; MAB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (trade or other name: ADB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (some trade or

other names: AB-PINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trade or other name: AB-FUBINACA);

N-[(1S)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (trade or other name: AB-CHMINACA);

N-hydroxy-3,4-methylenedioxyamphetamine (commonly referred to as N-hydroxy-alpha-methyl-3,4(methylenedioxy) phenethylamine, N-hydroxy MDA);

2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone (some trade or other names: 1-(1-pentyl-1H-indol-3-yl)-2-(2-methoxyphenyl)-ethanone; 1-pentyl-3-(2-methoxyphenylacetyl)indole; JWH-250);

Nifoxipam (some trade or other names: 5-(2-fluorophenyl)-1,3-dihydro-3-hydroxy-7- nitro-2H-1,4-benzodiazepin-2-one; 1,3-Dihydro-5-(2-fluorophenyl)-3-hydroxy-7-nitro- 2H-1,4-benzodiazepin-2-one; 3-hydroxydesmethylflunitrazepam; DP 370);

Nitrazolam (some trade or other names: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine);

Norflurazepam (some trade or other names: 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; nor-Flurazepam; N-Desalkylflurazepam; Desalkylflurazepam; Ro 5-3367);

1-Pentyl-3-(2-chlorophenylacetyl)indole (some trade or other names: JWH-203);

1-Pentyl-3-(4-cholor-1-naphthoyl)indole (some trade or other names: JWH-398);

1-Pentyl-3-[(4-methoxy)-benzoyl]indole (some trade or other names: SR-19; BTM-4; RCS-4);

1-Pentyl-3-(1-naphthoyl)indole-7118 (some trade or other names: JWH-018; AM678);

(1-pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (some trade or other

names: UR-144);

1-pentyl-N-(tricyclo[3.3.1.1^{3,7}]dec-1-yl-1H-indole-3 carboxamide (some trade or other names: APICA; JWH-018 adamantyl carboxamide; 2NE1; SDB-001);

1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (some trade or other names: 1-pentyl-1H-indole-3-carboxylic acid 8-quinolinyl ester; PB-22; QUPIC);

Phenazepam (some trade or other names: 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one; 7-bromo-5-(2-chlorophenyl)-1,2-dihydro-3H-1,4-benzodiazepin- 2-one; BD 98; Fenazepam; Elzepam; Phezipam; Phenorelaxan; Phenzitat);

Pyrazolam (some trade or other names: 8-bromo-1-methyl-6-(2-pyridinyl)-4H-(1,2,4)triazolo(4,3-a)(1,4)benzodiazepine; 8-bromo-1-methyl-6-(pyridin-2-yl)-4H-benzo[f][1,2,4]triazolo[4,3-a][1,4]diazepine; Pirazolam);

3,4,5-trimethoxyamphetamine;

Bufotenine (some trade or other names: 3-(beta-dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethyl-aminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine);

Diethyltryptamine (some trade or other names: DET; N,N-Diethyltryptamine);

Dimethyltryptamine (some trade or other names: DMT; N,N-DMT; N,N-Dimethyltryptamine);

Fluorophenylpiperazine (some trade or other names: FPP, pFPP, 2-fluorophenylpiperazine, 3-fluorophenylpiperazine, 4-fluorophenylpiperazine);

Gamma butyrolactone (some trade or other names: GBL, Gamma Buty Lactone, 4-butyrolactone, dihydro-2(3H)-furanone, tetrahydro-2-furanone, Gamma G, GH Gold);

Gamma hydroxy butyric acid (some trade or other names: GHB);

Ibogaine (some trade or other names: 7-ethyl-6, 6 beta, 7, 8, 9, 10, 12, 13-octahydro-2-

methoxy-6, 9-methano-5H-pyrido (1',2':1,2) azepino (5,4-b) indole; *Tabernanthe iboga*);

Lysergic acid diethylamide;

Marijuana;

Mescaline;

Methoxyphenylpiperazine (some trade or other names: MeOPP, pMPP, 4-MPP, 2-MeOPP, 3-MeOPP, 4-MeOPP);

Parahexyl (some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl);

Peyote (meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts);

N-benzylpiperazine (some trade or other names: BZP, 1-benzylpiperazine);

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocin;

Salvinorin A (some trade or other names: Divinorin A; Methyl (2S,4aR,6aR,7R,9S,10aS,10bR)-9-(acetyloxy)-2-(furan-3-yl)-6a,10b-dimethyl-4,10-dioxododecahydro-2H-benzofisochromene-7-carboxylate);

Ethylamine analog of phencyclidine (some trade or other names: N-ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE);

Pyrrolidine analog of phencyclidine (some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCPy; PHP);

1-(1-(2-thienyl)-cyclohexyl)-pyrrolidine (some trade or other names: TCPy);

Thiophene analog of phencyclidine (some trade or other names: 1-(1-(2-thienyl)-cyclohexyl)-piperidine; 2-thienyl analog of phencyclidine; TPCP; TCP); or

Trifluoromethylphenylpiperazine (some trade or other names: 1-(3-trifluoromethylphenyl)piperazine; 3-trifluoromethylphenylpiperazine; TFMPP).

 For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. All parts of the plant presently classified botanically as Datura, whether growing or not, the seeds thereof, any extract from any part of such plant or plants, and every compound, manufacture, salt derivative, mixture or preparation of such plant or plants, its seeds or extracts, unless substances consistent with those found in such plants are present in formulations that the Food and Drug Administration of the United States Department of Health and Human Services has approved for distribution.

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of phencyclidine, mecloqualone or methaqualone having a depressant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation.

7. Unless specifically excepted or unless listed in another schedule, any material,

compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers:

Alpha-PBP (some trade or other names: 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one, alpha- pyrrolidinobutiophenone);

Alpha-PVP (some trade or other names: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, alpha- pyrrolidinopentiophenone, alpha-pyrrolidinovalerophenone, O-2387);

Alpha-pyrrolidinoheptaphenone (some trade or other names: PV8);

Alpha-pyrrolidinohexanophenone (some trade or other names: alpha-PHP);

Aminorex;

Butylone (some trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1- one, β-keto-N-methylbenzodioxolylpropylamine, bk-MBDB);

Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone; alpha- aminopropiophenone; 2-aminopropiophenone; norephedrone);

4-chloro-alpha-pyrrolidinovalerophenone (some trade or other names: 4-chloro-a-PVP);

Dimethylone (some trade or other names: 3,4-methylenedioxy-N,Ndimethylcathinone; N,N-dimethyl MDCATH; N,N-dimethyl-3,4- methylenedioxycathinone; N,N-dimethylβ-keto-3,4-methylenedioxyamphetamine; 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)propan-1-one; bk-MDDMA);

N-ethylhexedrone;

Ethylone (some trade or other names: N-ethyl-3,4-methylenedioxycathinone; 1-(1,3- benzodioxol-5-yl)-2-(ethylamino)propan-1-one; MDEC; bk-MDEA);

N-ethylpentylone (1-(1,3-benzodioxol-5-yl)-2-ethylamino)-pentan-1-one) (some trade

or other names: ephylone);

Fenethylline;

Fluoroamphetamine (some trade or other names: 2-fluoroamphetamine, 3-fluoroamphetamine, 4-fluoroamphetamine, 2-FA, 3-FA, 4-FA, PFA);

Fluoromethcathinone (some trade or other names: 4-Fluoro-N-methylcathinone, 1-(4-fluorophenyl)-2-(methylamino)propan-1-one, 4-Fluoromethcathinone (Flephedrone), 4- FMC, 3-Fluoro-N-methylcathinone, 1-(3-fluorophenyl)-2-2(methylamino)propan-1- one, 3-Fluoromethcathinone, 3-FMC, 2-Fluoro-N-methylcathinone, 1-(2-fluorophenyl)- 2-(methylamino)propan-1-one, 2-FMC);

Mephedrone (some trade or other names: Methylmethcathinone, 4-Methylmethcathinone, 4-MMC, 4-Methylephedrone);

Methamphetamine;

Methcathinone (some trade or other names: N Methylcathinone,cat);

Methedrone (some trade or other names: Methoxymethcathinone, 4-Methoxymethcathinone, bk-PMMA, methoxyphedrine);

4-methyl-alpha-ethylaminopentiophenone (some trade or other names: 4-MEAP);

4’-methyl-alpha-pyrrolidinohexiophenone (some trade or other names: MPHP);

4-methyl-alpha-pyrrolidinopropiophenone (some trade or other names: 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one, 4-MePPP);

(±)cis-4-methylaminorex ((+)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

Methylenedioxypyrovalerone (some trade or other names: 3,4-Methylenedioxypyrovalerone, MDPV);

Methylethcathinone (some trade or other names: 2-(ethylamino)-1-(4-

methylphenyl)propan-1-one, 4-MEC, 4-methyl-N-ethylcathinone);

Methylone (some trade or other names: Methylenedioxy-N-methylcathinone, Methylenedioxymethcathinone, 3,4-Methylenedioxy-N-methylcathinone, bk-MDMA);

N,N-dimethylamphetamine (commonly referred to as N,N-alpha-trimethyl-benzeneethanamine; N,N-alpha-trimethylphenethylamine);

N-ethylamphetamine;

Naphyrone (some trade or other names: 1-(naphthalen-2-yl)-2(pyrrolidin-1-yl)pentan-1-one, naphthylpyrovalerone, naphpyrovalerone, NRG-1, O-2482);

Pentedrone (some trade or other names: 2-(methylamino)-1-phenylpentan-1-one, α- methylaminovalerophenone); or

Pentylone (trade or other names: 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one; beta-keto-methylbenzodioxolylpentanamine; bk-MBDP; bk-methyl-K).

8. Unless specifically listed in another schedule, coca leaves, cocaine base or free base, or a salt, compound, derivative, isomer or preparation thereof which is chemically equivalent or identical to such substances, and any quantity of material, compound, mixture or preparation which contains coca leaves, cocaine base or cocaine free base or its isomers or any of the salts of cocaine, except decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

9. Unless specifically listed in another schedule, Tetrahydrocannabinols (natural or synthetic equivalents of substances contained in the plant, or in the resinous extractives of Cannabis, sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

Delta 9 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 8 cis or trans tetrahydrocannabinol, and their optical isomers, also known as Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers;

Tetrahydrocannabinols contained in the genus Cannabis or in the resinous extractives of the genus Cannabis;

Synthetic equivalents of tetrahydrocannabinol substances or synthetic substances, derivatives and their isomers with a similar chemical structure; and

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions covered).

10. Unless specifically listed in another schedule and except as otherwise provided in subsection 11, any material, compound, mixture or preparation which contains any quantity of CBD (natural or synthetic equivalents of the substances contained in the plant or in the resinous extractives of Cannabis sp. or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity).

11. A drug product which:

(a) Has been approved by the United States Food and Drug Administration;

(b) Contains CBD derived from any plant in the genus Cannabis or the resinous extractives thereof; and

(c) Contains not more than 0.1 percent residual THC by weight,

➥ is not a controlled substance.

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

Proposed Scheduling: Adding Tianeptine to Schedule I

Section 1: Summary

The Nevada State Board of Pharmacy, pursuant to NRS 453.146, proposes the placement of Tianeptine to Schedule I.

Section 2: Background

NRS 453.146 Powers and duties of Board.
The Board shall administer the provisions of NRS 453.011 to 453.552, inclusive, and may add substances to or delete or reschedule all substances enumerated in schedules I, II, III, IV and V by regulation.

In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;
2. The scientific evidence of its pharmacological effect, if known;
3. The state of current scientific knowledge regarding the substance;
4. The history and current pattern of abuse;
5. The scope, duration and significance of abuse;
6. The risk to the public health;
7. The potential of the substance to produce psychic or physiological dependence liability; and
8. Whether the substance is an immediate precursor of a controlled substance.

Section 3: Evaluation of the Scheduling Criteria

1. The actual or relative potential for abuse;

Tianeptine is an atypical tricyclic antidepressant that is not approved by the U.S. Food and Drug Administration (FDA). The drug (marketed as Coaxil or Stablon) is approved for use in Europe, Asia, and Latin America.[1] In the U.S., tianeptine is known as ZaZa and Tianna Red by some users, who can find it readily available in gas stations, convenience stores, and online.

Tianeptine was developed to help increase serotonin uptake in the brain; it can also act as a full agonist at the mu-opioid receptor. As a full agonist, it produces a euphoric high and carries a significant risk of overdose. Furthermore, its short half-life can lead to rapid withdrawal, increasing its potential for addiction and misuse.[2]

Similar to opioid withdrawal, patients who experience tianeptine withdrawal commonly present with neurologic effects (e.g., agitation, anxiety, drowsiness), cardiovascular effects (e.g., tachycardia, hypertension), and gastrointestinal effects (e.g., nausea, vomiting, diarrhea, abdominal cramps).[3]

A medical literature review conducted in 2017, found 18 cases of individuals experiencing tianeptine misuse, dependence, and abuse. The review found higher frequency of tianeptine abuse/dependence was observed in women and 30- to 45-year-olds. Most cases (n = 13) reported a previous history of substance abuse. The therapeutic dose of tianeptine was exceeded 110-fold (i.e., up to 4125 mg/day) with a mean of about 1469 mg/day. The most prominent phenomena associated with tianeptine abuse and dependence were marked euphoria and withdrawal symptoms perpetuating further drug misuse.[4]

According to the U.S. Centers for Disease Control and Prevention (CDC), case reports demonstrate that tianeptine toxicity mimicked opioid toxicity and that naloxone was an effective therapy.[5,6] Tolerance to tianeptine and withdrawal have been reported. Neonatal abstinence syndrome mimicking opioid neonatal abstinence syndrome has occurred after tianeptine dependence during pregnancy.[7]

2. The scientific evidence of its pharmacological effect, if known;

Clinical effects of tianeptine abuse can mimic opioid toxicity and withdrawal due to its strong affinity at the mu-opioid receptors and through increases in extracellular dopamine concentrations throughout cerebral tissue.[2] One study examining the effect of the compound on rats, found that tianeptine produces mu-opioid receptor agonist-like acute adverse effects that include motor impairment, constipation, and respiratory depression.[8]

Additional evidence demonstrates that tianeptine mimics opioid toxicity due to reports of tianeptine toxicity being reversed with naloxone. Dempsey and others (2017) document a case report of a 36-year-old male intentionally injected tianeptine powder intravenously and, as a result, became unresponsive. The authors noted that "his toxicity was successfully reversed with two doses of naloxone 0.4 mg IV.[9]

In February 2022, the FDA issued a consumer update on tianeptine products linked to serious harm, overdoses, and death. In the alert, the agency notes that it has identified cases in which people experienced other serious harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and anti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.[10]

3. The state of current scientific knowledge regarding the substance;

Tianeptine is an atypical antidepressant approved for use in Europe, Asia, and Latin America. The drug has not been approved by the United States Food and Drug Administration (FDA) for any medical use nor are there any commercial uses for tianeptine in the United States.

As stated previously, the clinical effects of tianeptine abuse can mimic opioid toxicity and withdrawal due to its strong affinity at the mu-opioid receptors and through increases in extracellular dopamine concentrations throughout cerebral tissue.[2] One study examining the effect of the compound on rats, found that tianeptine produces mu-opioid receptor agonist-like acute adverse effects that include motor impairment, constipation, and respiratory depression.[8] Neonatal abstinence syndrome mimicking opioid neonatal abstinence syndrome has occurred after tianeptine dependence during pregnancy.[7]

In February 2022, the FDA issued a consumer update on tianeptine products linked to serious harm, overdoses, and death. In the alert, the agency notes that it has identified cases in which people experi-

enced other serious harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and anti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.[10]

4. The history and current pattern of abuse;

The history and current pattern of abuse can be illustrated by a recent review of exposure calls related to tianeptine reported by poison control centers to the National Poison Data System (NPDS) from 2000 to 2017. From 2000 to 2017, NPDS received 218 calls related to tianeptine exposure, including one from outside the United States. Tianeptine-only exposures, excluding 29 withdrawal-associated calls, accounted for 114 (52.3%) calls. During the first 14 years of the study period (2000–2013), NPDS received a total of 11 tianeptine exposure calls. From 2014 through 2017, there was a statistically significant increase in calls related to exposure ($p<0.001$) and intentional abuse or misuse ($p<0.001$). The total number of tianeptine exposure calls increased from five in 2014 to 38 in 2015, 83 in 2016, and 81 in 2017.[10]

A similar review conducted by Alabama's poison control centers found an increase in tianeptine toxicity beginning in May 2019. The review found eighty-four cases of atypical tricyclic antidepressants were identified in the study period. Forty-eight cases involving tianeptine met inclusion criteria and were reviewed. Of these, 37 (77%) occurred from May 2019 to March 2020. Twenty-seven (56%) required medical admission including 17 cases (35%) that were managed in an intensive care unit. Seventeen of the 48 cases resulted from acute tianeptine intoxication. Lethargy was the most common presentation, but some patients also presented with agitation. Thirty-one (65%) of the cases resulted from tianeptine withdrawal, which usually exhibited agitation, anxiety, gastrointestinal distress. Naloxone was used in 4 cases (24%) of the acute intoxication cohort and benzodiazepines were frequently used both in acutely intoxicated patients and in patients experiencing tianeptine withdrawal.[11]

Although tianeptine is not approved for use by the FDA, it is readily available for purchase as a dietary supplement or research chemical. Several online discussion forums among users describe the euphorigenic effects of tianeptine. In a 2018 Morbidity and Mortality Weekly Report from CDC, the authors conclude that "…in light of the ongoing U.S. opioid epidemic, any emerging trends in drugs with opioid-like effects raise concerns about potential abuse and public health safety."[1]

5. The scope, duration and significance of abuse;

To characterize tianeptine exposures in the United States, CDC analyzed all exposure calls related to tianeptine reported by poison control centers to the National Poison Data System (NPDS) from 2000 to 2017. CDC found that tianeptine exposure calls, including those for intentional abuse or misuse, increased across the United States during 2014–2017. Most tianeptine exposures occurred among persons aged 21–40 years and resulted in moderate outcomes. Neurologic, cardiovascular, and gastrointestinal signs and symptoms were the most commonly reported health effects, with some effects mimicking opioid toxicity. A substantial number of tianeptine exposure calls also reported clinical effects of withdrawal. Among 83 tianeptine exposures with noted coexposures, the most commonly reported coexposures were to phenibut, ethanol, benzodiazepines, and opioids.[1]

From 2000 to 2017, NPDS received 218 calls related to tianeptine exposure, including one from outside the United States. Tianeptine-only exposures, excluding 29 withdrawal-associated calls, accounted for 114 (52.3%) calls. During the first 14 years of the study period (2000–2013), NPDS received a total of 11 tianeptine exposure calls. From 2014 through 2017, there was a statistically significant increase in calls related to exposure ($p<0.001$) and intentional abuse or misuse ($p<0.001$). The total number of tianeptine exposure calls increased from five in 2014 to 38 in 2015, 83 in 2016, and 81 in 2017.[1]

6. The risk to the public health;

The availability of an unregulated, tricyclic antidepressant without any medical supervision presents a serious risk to public health. Media reports indicate that patients are utilizing tianeptine to either manage withdrawal or initiating use based upon the reported opioid-like effects.[12] Additionally, reports indicate that such unregulated access leads patients to consuming tianeptine at doses higher than the doses prescribed in the countries where the drug has been approved.[13] Further, the compound is not subject to the same FDA regulatory scheme – including inspections of manufacturing facilities, quality assurance testing, and adverse event monitoring – as other tricyclic antidepressants approved for use in the United States.

According to CDC, case reports demonstrate that tianeptine toxicity mimicked opioid toxicity and that naloxone was an effective therapy.[5] Tolerance to tianeptine and withdrawal have been reported.[15] Neonatal abstinence syndrome mimicking opioid neonatal abstinence syndrome has occurred after tianeptine dependence during pregnancy.[7]

Although tianeptine is not approved for use by the FDA, it is readily available for purchase as a dietary supplement or research chemical. Several online discussion forums among users describe the euphoric effects of tianeptine. In a 2018 Morbidity and Mortality Weekly Report from CDC, the authors conclude that "in light of the ongoing U.S. opioid epidemic, any emerging trends in drugs with opioid-like effects raise concerns about potential abuse and public health safety."[1]

In February 2022, the FDA issued a consumer update on tianeptine products linked to serious harm, overdoses, and death. In the alert, the agency notes that it has identified cases in which people experienced other serious harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and an-ti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.[10]

7. The potential of the substance to produce psychic or physiological dependence liability; and

While tianeptine is approved for use in other counties, many countries have banned or withdrawn this medication from the market due to concerns regarding addiction and other adverse events. In the country of Georgia, the health authority withdrew tianeptine from the market in June 2010, and the health authorities of Russia and Armenia classified tianeptine as a controlled substance in July 2010. Similar measures were implemented in Ukraine in January 2011.[16] Tianeptine has been described to have a similar risk for diversion as diazepam, ranking first among various antidepressants for doctor-shopping in France.[17] Several states, including Alabama, Michigan, Mississippi, Tennessee, Georgia, Indiana, Ohio, Florida, and Kentucky have taken action to ban or strictly control tianeptine sales at the state level.[18]

In January, House lawmakers called on FDA Commissioner Dr. Robert Califf to crack down on the use of tianeptine. The letter stated, "The FDA first issued a warning on tianeptine use in 2018, noting that users may "inadvertently find themselves addicted to tianeptine and should avoid all products containing this ingredient." Your agency issued an additional warning in 2022, warning that reports indicate that "tianeptine has a potential for abuse." And in November 2023, FDA issued a warning for consumers not to purchase or use any products sold under the brand Neptune's Fix that contain tianeptine after reports of severe adverse events by users including seizures and hospitalizations. While we appreciate these warnings, we believe that more action on tianeptine use is needed to ensure the health and well-being of the American people."

A medical literature review conducted in 2017, found 18 cases of individuals experiencing tianeptine misuse, dependence, and abuse. The review found higher frequency of tianeptine abuse/dependence was

observed in women and 30- to 45-year-olds. Most cases (n = 13) reported a previous history of substance abuse. The therapeutic dose of tianeptine was exceeded 110-fold (i.e., up to 4125 mg/day) with a mean of about 1469 mg/day. The most prominent phenomena associated with tianeptine abuse and dependence were marked euphoria and withdrawal symptoms perpetuating further drug misuse.[4]

8. Whether the substance is an immediate precursor of a controlled substance.

This substance is not known to be an immediate precursor.

References

1. El Zahran T, Schier J, Glidden E, et al. Characteristics of Tianeptine Exposures Reported to the National Poison Data System — United States, 2000–2017. MMWR Morb Mortal Wkly Rep 2018;67:815–818. DOI: http://dx.doi.org/10.15585/mmwr.mm6730a2
2. Edinoff AN, Sall S, Beckman SP, Koepnick AD, Gold LC, Jackson ED, Wenger DM, Cornett EM, Murnane KS, Kaye AM, Kaye AD. Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review. Pain Ther. 2023 Oct;12(5):1121-1134. doi: 10.1007/s40122-023-00539-5. Epub 2023 Jul 15. PMID: 37453966; PMCID: PMC10444703.
3. William Rushton, Brian Whitworth, Julie Brown, Michael Kurz & Jessica Rivera (2021) Characteristics of tianeptine effects reported to a poison control center: a growing threat to public health, Clinical Toxicology, 59:2, 152-157, DOI: 10.1080/15563650.2020.1781151
4. Springer J, Cubała WJ. Tianeptine Abuse and Dependence in Psychiatric Patients: A Review of 18 Case Reports in the Literature. J Psychoactive Drugs. 2018 Jul-Aug;50(3):275-280. doi: 10.1080/02791072.2018.1438687. Epub 2018 Mar 1. PMID: 29494783.
5. Dempsey SK, Poklis JL, Sweat K, Cumpston K, Wolf CE. Acute toxicity from intravenous use of the tricyclic antidepressant tianeptine. J Anal Toxicol 2017;41:547–50.
6. Ari M, Oktar S, Duru M. Amitriptyline and tianeptine poisoning treated by naloxone. Hum Exp Toxicol 2010;29:793–5
7. Bence C, Bonord A, Rebillard C, et al. Neonatal abstinence syndrome following tianeptine dependence during pregnancy. Pediatrics 2016;137:e20151414
8. Baird TR, Akbarali HI, Dewey WL, Elder H, Kang M, Marsh SA, Peace MR, Poklis JL, Santos EJ, Negus SS. Opioid-like adverse effects of tianeptine in male rats and mice. Psychopharmacology (Berl). 2022 Jul;239(7):2187-2199. doi: 10.1007/s00213-022-06093-w. Epub 2022 Feb 24. PMID: 35211768; PMCID: PMC10055856.
9. Dempsey SK, Poklis JL, Sweat K, Cumpston K, Wolf CE. Acute Toxicity From Intravenous Use of the Tricyclic Antidepressant Tianeptine. J Anal Toxicol. 2017 Jul 1;41(6):547-550. doi: 10.1093/jat/bkx034. PMID: 28541419; PMCID: PMC6075028
10. https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death
11. William Rushton, Brian Whitworth, Julie Brown, Michael Kurz & Jessica Rivera (2021) Characteristics of tianeptine effects reported to a poison control center: a growing threat to public health, Clinical Toxicology, 59:2, 152-157, DOI: 10.1080/15563650.2020.1781151
12. Tianeptine, or 'Gas Station Heroin,' Causes Intense Withdrawals And It's Mostly Legal (vice.com)
13. https://www.vice.com/en/article/88q3va/tianeptine-gas-station-heroin-legal-in-most-states
14. Kisa C, Bulbul DO, Aydemir C, Goka E. Is it possible to be dependent to Tianeptine, an antidepressant? A case report. Prog Neuropsychopharmacol Biol Psychiatry. 2007 Apr 13;31(3):776-8. doi: 10.1016/j.pnpbp.2007.01.002. Epub 2007 Jan 16. PMID: 17270334.
15. Rahul Lauhan, Alan Hsu, Al Alam, Kristin Beizai,Tianeptine Abuse and Dependence: Case Report and Literature Review, Psychosomatics. 2018:59:547-553, ISSN 0033-3182, https://doi.org/10.1016/j.psym.2018.07.006
16. Durmus N, Ozbilen G, Kasap Y, et al. Risk management in tianeptine abuse in Turkey: a national experience. Bulletin of Clinical Psychopharmacology 2013;23:149–54.
17. Rahul Lauhan, Alan Hsu, Al Alam, Kristin Beizai, Tianeptine Abuse and Dependence: Case Report and Literature Review, Psychosomatics, Volume 59, Issue 6, 2018, Pages 547-553, ISSN 0033-3182, https://doi.org/10.1016/j.psym.2018.07.006
18. https://www.forbes.com/sites/tylerroush/2023/03/24/growing-danger-of-gas-station-heroin-kentucky-latest-state-to-b/?sh=1136e1955ef5

U.S. FOOD & DRUG ADMINISTRATION

January 11, 2024

To Whom it May Concern:

The U.S. Food and Drug Administration (FDA) issued a public safety alert on November 21, 2023, after receiving multiple reports of serious medical injuries related to "Neptune's Fix." Neptune's Fix is labeled to contain the dangerous and addictive ingredient tianeptine. Tianeptine is not approved for any medical use in the United States and is often unlawfully labeled or sold as a dietary supplement. FDA continues to receive reports of consumers who have suffered seizures, loss of consciousness or other adverse health events after ingesting this product. **We are reaching out because most consumers report purchasing this product at local gas stations or convenience stores across the country.**

FDA is urging all retailers to STOP selling Neptune's Fix and any tianeptine-containing products. We are asking that trade associations please share the message above and information below to keep consumers safe:

- FDA warns consumers not to purchase or use Neptune's Fix or any tianeptine product due to serious risks: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-purchase-or-use-neptunes-fix-or-any-tianeptine-product-due-serious-risks
- Tianeptine Products Linked to Serious Harm, Overdoses, Death: https://www.fda.gov/consumers/consumer-updates/tianeptine-products-linked-serious-harm-overdoses-death

Further, FDA is actively investigating new reports in conjunction with local and state health departments. We are also aware that Neptune's Fix and other tianeptine-containing products are sold illegally online and in other retail locations. At least twelve states have banned the sale of tianeptine.

U.S. Food and Drug Administration
Office of Regulatory Affairs
Rockville, MD 20857

U.S. FOOD & DRUG ADMINISTRATION

According to the CDC, the clinical effects of tianeptine abuse and withdrawal can mimic opioid toxicity/withdrawal.

Consumers and retailers should report adverse events or side effects related to the use of Neptune's Fix and similar products to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at MedWatch Online Voluntary Reporting Form, or;
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

Please respond to this email for any additional information or clarification.

Sincerely,

Health Fraud Branch
Office of Regulatory Affairs
U.S. Food and Drug Administration
FDAAdvisory@fda.hhs.gov

Country	Entity	License requirement	License review policy	Federal Register citation
	R2, Sharjah Airport Free Zone Street, Office 806, Sharjah, United Arab Emirates; *and* PO Box 120683, Saif-Zone, Sharjah, United Arab Emirates; *and* . SM-Office E1–1414D, Ajman Free Zone, Ajman, United Arab Emirates.			
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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–26935 Filed 12–5–23; 11:15 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

Federal Old-Age, Survivors and Disability Insurance (1950–)

CFR Correction

This rule is being published by the Office of the Federal Register to correct an editorial or technical error that appeared in the most recent annual revision of the Code of Federal Regulations.

■ In Title 20 of the Code of Federal Regulations, Parts 400 to 499, revised as of April 1, 2023, in Appendix I to Subpart P of Part 404, in Part B, section 101.00, revise the first sentence of paragraph C.7.c. to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part B

* * * * *

101.00 Musculoskeletal Disorders.

* * * * *

C. * * *

7. * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. * * *

[FR Doc. 2023–26983 Filed 12–6–23; 8:45 am]

BILLING CODE 0099–10–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1036]

Schedules of Controlled Substances: Placement of Nine Specific Fentanyl-Related Substances in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places nine fentanyl-related substances, as identified in this final rule, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act. These nine fentanyl-related substances are currently listed in schedule I pursuant to a temporary scheduling order. This action makes permanent the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle these nine specific fentanyl-related controlled substances.

DATES: *Effective date:* December 7, 2023.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION: In this rule, the Drug Enforcement Administration (DEA) is permanently scheduling the following nine controlled substances including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I of the Controlled Substances Act (CSA):

- *meta*-fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide),
- *meta*-fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide),
- *para*-methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- 3-furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide),
- 2′,5′-dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide),
- isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide),
- *ortho*-fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide),
- *alpha*′-methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide), and
- *para*-methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide).

Legal Authority

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS);[1] or (3) on the petition of any interested party.[2] This action was initiated on the Attorney General's own motion, as delegated to the Administrator of the DEA (Administrator), and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] 21 U.S.C. 811(a).

(Assistant Secretary) and an evaluation of all relevant data by DEA. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles or proposes to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl.

Background

On February 6, 2018, DEA published an order in the **Federal Register** (FR) (83 FR 5188) amending 21 CFR 1308.11(h), temporarily placing fentanyl-related substances, as defined in that order, in schedule I of the CSA based upon a finding that these substances pose an imminent hazard to the public safety and pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The nine substances named in this final rule meet the existing definition of fentanyl-related substances, as they are not otherwise controlled in any other schedule (i.e., not included under another DEA Controlled Substance Code Number) and are structurally related to fentanyl by one or more of the five modifications listed under the definition. That temporary scheduling order was effective on the date of publication and was based on findings by the former Acting Administrator that the temporary scheduling of these substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Pursuant to 21 U.S.C. 811(h)(2), the temporary control of fentanyl-related substances, a class of substances as defined in the order, as well as these nine specific substances already covered by that order, was set to expire on February 6, 2020. However, on February 6, 2020, as explained in DEA's April 10, 2020, correcting amendment (85 FR 20155), Congress extended that expiration date until May 6, 2021, by enacting the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act (Pub. L. 116–114, sec. 2, 134 Stat. 103). This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.

Comment: One commenter stated that fentanyl and the list of related substances is a hazard due to the overdose deaths that have been occurring. This commenter also referenced the National Institute on Drug Abuse, stating that fentanyl-related overdoses have been increasing in the United States. Lastly, this commenter stated that permanently placing fentanyl and the list of related substances in schedule I would improve public health and allow for regulation of these substances.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note is that fentanyl remains a schedule II substance. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Comment: One commenter stated the proposed rule would make it more difficult to produce and distribute these dangerous fentanyl-related substances, which would help combat the opioid epidemic in the United States. This commenter also referenced a news article by National Public Radio, stating that these nine fentanyl-related substances are not currently classified as controlled substances, making it easy to produce and distribute these substances without legal consequences. Lastly, this commenter recognized that this proposal could have significant impacts on the healthcare industry, such as increased oversight and regulation of fentanyl-related substances, which could prevent their misuse and abuse.

DEA Response: DEA appreciates the comments in support of this rulemaking. One clarification to note based on the comment above is that, by temporary order on February 6, 2018, DEA placed these nine fentanyl-related substances under schedule I. 83 FR 5188. That temporary order defined a fentanyl-related substance to mean any substance not otherwise controlled in any schedule (*i.e.,* not listed under another DEA Controlled Substance Code Number), and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), that is structurally related to fentanyl by one or more of five specified structural modifications. Therefore, these nine fentanyl-related substances are in fact already schedule I controlled substances.

The final rule being issued today applies to nine fentanyl-related substances that were the subject of a February 6, 2018, temporary scheduling order. These nine substances will now be listed in 21 CFR 1308.11(b), as specified in the text of the rule that appears below. This final rule should not have a significant impact on the healthcare industry because these nine fentanyl-related substances have no medical use and they have already been added as schedule I controlled substances since 2018.

Comment: One commenter discussed the direct and indirect effects on federal and state healthcare from this regulation. The commenter suggested that this regulation will boost federal oversight of manufacturing and disseminating harmful chemicals. In addition, this regulation would limit availability and expected use, ensure protection of residents, and increases confidence in the medical field. In addition, the commenter stated that is critical to restrict the use of ''fentanyl replicates'' to those who may need them for medical conditions. Lastly, the commenter stated that raising awareness of the risks of abusing these drugs benefits their prevention.

DEA Response: DEA appreciates the comments in support of this rulemaking. As mentioned previously, FDA has not approved a marketing application for a drug product containing any of these nine substances for any therapeutic indication. These substances have no medical use in the United States.

Comment: One commenter stated that this rule will affect federal healthcare because many federal agencies are trying to tackle the opioid crisis. The commenter discussed the rising number of pediatric deaths from fentanyl in 2021 and the surge in 2018 of fentanyl overdoses among older adolescents as well as in children younger than five. The commenter agrees with this final rule to schedule these fentanyl-related substances. The commenter also stated that fentanyl is highly addictive and that while fentanyl is prescribed for chronic pain or major surgery, it should be a last resort.

DEA Response: DEA appreciates the comments in support of this rulemaking.

Comment: One commenter agreed with this final rule to make permanent these nine specific fentanyl-related substances rather than continuing multiple temporary extensions. Once finalized, the commenter stated that the federal government could act against anyone handling these substances since over 150 people die each day from a fentanyl-related drug overdose.

DEA Response: DEA appreciates the comments in support of this rulemaking. Again, DEA notes that fentanyl is a schedule II controlled substance that can be prescribed for approved medical uses. However, the nine fentanyl-related substances addressed in this rule are already

schedule I controlled substances and none of them have any medical use in the United States.

Comment: One commenter stated that fentanyl should be placed in schedule I. The commenter compared this substance to marijuana, which is a schedule I drug and thought it was mind-blowing that fentanyl was not a schedule I substance. It was suggested that the rising number of deaths, the risk to public health, abuse potential, and dependency should classify fentanyl as a schedule I.

DEA Response: DEA appreciates this comment. As stated previously, fentanyl remains a schedule II substance. Fentanyl has approved medical uses in the United States. This final rule only applies to the fentanyl-related substances that are listed in this final order.

Scheduling Conclusion

After consideration of the relevant matter presented through public comments, the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl. DEA is permanently scheduling these nine fentanyl-related substances as schedule I controlled substances under the CSA.

Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule.[3] After consideration of the analysis and recommendation of the Assistant Secretary for HHS and review of all other available data, the Administrator, pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds the following:

(1) The abuse potential of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl is associated with each substance's pharmacological similarity to other schedule I and II mu-opioid receptor agonist substances which have a high potential for abuse. Similar to morphine (schedule II), fentanyl (schedule II), and several schedule I opioid substances that are structurally related to fentanyl, these nine fentanyl-related substances have been shown to bind and act as mu-opioid receptor agonists;

(2) *meta*-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, have no currently accepted medical use in treatment in the United States;[4] and

(3) There is a lack of accepted safety for use of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl under medical supervision.

Based on these findings, the Administrator concludes that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, warrant control in schedule I of the CSA.[5]

This final rule does not affect the scheduling of fentanyl itself, which remains a schedule II controlled substance.

Requirements for Handling Meta-Fluorofentanyl, Meta-Fluoroisobutyryl Fentanyl, Para-Methoxyfuranyl Fentanyl, 3-Furanyl Fentanyl, 2′,5′-Dimethoxyfentanyl, Isovaleryl Fentanyl, Ortho-Fluorofuranyl Fentanyl, Alpha′-Methyl Butyryl Fentanyl, and Para-Methylcyclopropyl Fentanyl

Meta-Fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl will continue, on a permanent basis,[6] to be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, or who desires to handle these nine substances, is required to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of these substances in a manner not authorized by the CSA is unlawful and those in possession of any quantity of these substances may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks. meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-

[3] 21 U.S.C. 812(b).

[4] Although there is no evidence suggesting that *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. The drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992).

[5] 21 U.S.C. 812(b)(1).

[6] *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and/or *para*-methylcyclopropyl fentanyl have been subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h), by virtue of the February 6, 2018 temporary scheduling order (83 FR 5188) and the subsequent statutory extension of that order through December 31, 2024 (Pub. L. 117–328, Division O, Title VI, Sec. 601).

dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security. meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 823, and in accordance with 21 CFR 1301.71–1301.76. Non-practitioners handling these nine substances must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels and labeling for commercial containers of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, must be in compliance with 21 U.S.C. 825, and be in accordance with 21 CFR part 1302.

5. *Quota.* Only registered manufacturers are permitted to manufacture *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303.

6. *Inventory.* Any person registered with DEA to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must have an initial inventory of all stocks of controlled substances (including these substances) on hand on the date the registrant first engages in the handling of controlled substances pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

After the initial inventory, every DEA registrant must take a new inventory of all stocks of controlled substances (including *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl) on hand every two years pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant must maintain records and submit reports with respect to *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1301.74(b) and (c), 1301.76(b), 1307.11 and parts 1304, 1312, and 1317. Manufacturers and distributors must submit reports regarding these substances to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312.

8. *Order Forms.* Every DEA registrant who distributes *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must continue to comply with the order form requirements, pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl must comply with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl not authorized by, or in violation of, the CSA or its implementing regulations is unlawful and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders (E.O.) 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This action is not a significant regulatory action as defined by Executive Order (E.O.) 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in E.O. 13563 (Improving Regulation and Regulatory Review); and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB). This action makes no change in the status quo, as *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl are already listed as a schedule I controlled substances.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the National Government and the states, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601–602, has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small

entities. On February 6, 2018, DEA published an order to temporarily place fentanyl-related substances in schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). DEA estimates that all entities handling or planning to handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl have already established and implemented the systems and processes required to handle these substances.

As discussed in the NPRM, there are 108 registrations authorized to handle one or more of the following substances: *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, as well as a number of registered analytical labs that are authorized to handle schedule I controlled substances generally. These 108 registrations represent a maximum of 95 small entities. Therefore, DEA conservatively estimates as many as 95 small entities are affected by this rule.

A review of the 108 registrations indicates that all entities that currently handle *meta*-fluorofentanyl, *meta*-fluoroisobutyryl fentanyl, *para*-methoxyfuranyl fentanyl, 3-furanyl fentanyl, 2′,5′-dimethoxyfentanyl, isovaleryl fentanyl, *ortho*-fluorofuranyl fentanyl, *alpha*′-methyl butyryl fentanyl, and *para*-methylcyclopropyl fentanyl, also handle other schedule I controlled substances and have established and implemented (or maintain) the systems and processes required to handle these substances. Therefore, DEA anticipates that this final rule will impose minimal or no economic impact on any affected entities, and, thus, will not have a significant economic impact on any of the small entities. Therefore, DEA has concluded that this final rule will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined and certifies that this action would not result in any federal mandate that may result ''in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year * * * .'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This final rule does not impose a new collection or modify an existing collection of information under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. Also, this final rule does not impose new or modify existing recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. However, this final rule does require compliance with the following existing OMB collections: 1117–0003, 1117–0004, 1117–0006, 1117–0008, 1117–0009, 1117–0010, 1117–0012, 1117–0014, 1117–0021, 1117–0023, 1117–0029, and 1117–0056. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. Pursuant to the CRA, DEA is submitting a copy of this final rule to both Houses of Congress and to the Comptroller General.

Determination To Make Rule Effective Immediately

As indicated above, this rule finalizes the schedule I control status of nine substances that has already been in effect. These nine substances all fall within the definition of fentanyl-related substances set forth in the February 6, 2018, temporary scheduling order (83 FR 5188). Through the Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act, which became law on February 6, 2020, Congress extended the temporary control of fentanyl-related substances until May 6, 2021. This temporary order was subsequently extended multiple times, most recently on December 29, 2022, through the Consolidated Appropriations Act, 2023, which extended the order until December 31, 2024.[7] The February 2018 order was effective on the date of publication, and was based on findings by the then-Acting Administrator that the temporary scheduling of the fentanyl-related substances was necessary to avoid an imminent hazard to the public safety pursuant to 21 U.S.C. 811(h)(1). Because this rule finalizes the control status of nine substances that has already been in effect, it does not alter the legal obligations of any person who handles these substances. Rather, it merely makes permanent the current scheduling status and corresponding legal obligations. Therefore, since this rule does not change the current scheduling status and corresponding legal obligations, DEA is making the rule effective on the date of publication in the **Federal Register**, as any delay in the effective date is unnecessary and would be contrary to the public interest.

[7] Public Law 117–328, Division O, Title VI, Sec. 601.

Signing Authority

This document of the Drug Enforcement Administration was signed on November 29, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(10) through (94) to read as follows:

Old paragraph	New paragraph
(b)(10) through (33)	(b)(11) through (34).
(b)(34) through (43)	(b)(36) through (45).
(b)(44) through (47)	(b)(47) through (50).
(b)(48) through (50)	(b)(52) through (54).
(b)(51) through (66)	(b)(57) through (72).
(b)(67) through (74)	(b)(74) through (81).
(b)(75) through (94)	(b)(84) through (103).

■ b. Add new paragraphs (b)(10), (35), (46), (51), (55), (56), (73), (82), and (83);

The additions to read as follows:

§ 1308.11 Schedule I.

(b) * * *

* * * * *

*	*	*	*	*	*	*
(10) *alpha'*-Methyl butyryl fentanyl (2-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)						9864
*	*	*	*	*	*	*
(35) 2′,5′-Dimethoxyfentanyl (*N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide)						9861
*	*	*	*	*	*	*
(46) 3-Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide)						9860
*	*	*	*	*	*	*
(51) Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide)						9862
*	*	*	*	*	*	*
(55) *meta*-Fluorofentanyl *(N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide)						9857
(56) *meta*-Fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide)						9858
*	*	*	*	*	*	*
(73) *ortho*-Fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)						9863
*	*	*	*	*	*	*
(82) *para*-Methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide						9859
(83) *para*-Methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide)						9865

* * * * *

[FR Doc. 2023–26694 Filed 12–6–23; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF STATE

22 CFR Part 42

[Public Notice: 12224]

RIN 1400–AE83

Immigrant Visas

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State (''Department'') is amending its regulation governing immigrant visas by removing the section which allows a consular officer to conduct an informal evaluation of the family members of an immigrant visa applicant to identify potential grounds of ineligibility. The existing regulation was promulgated in 1952, at a time when a consular officer could more readily assess a family member's potential qualification for a visa without a formal visa application. Assessing eligibility for an immigrant visa is now a more complex task and not one which can be accomplished accurately with an informal evaluation.

DATES: This final rule is effective on January 8, 2024.

FOR FURTHER INFORMATION CONTACT: Claire Kelly, Office of Visa Services, Bureau of Consular Affairs, Department of State; telephone (202) 485–7586, *VisaRegs@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published a notice of proposed rulemaking, Public Notice 11604 at 88 FR 16384 (Mar. 17, 2023) (hereafter ''proposed rule''), with a request for comments, proposing to amend Part 42 of Title 22 of the Code of Federal Regulations. The rule will eliminate 22 CFR 42.68 in its entirety. The regulatory amendment was discussed in detail in the proposed rule, and that discussion is adopted by reference in this final rule. The Department received two responsive comments, both in support of eliminating 22 CFR 42.68. The Department is now promulgating a final rule with no changes from the proposed rule. This rule results in no change for applicants, as the authority granted by 22 CFR 42.68 was no longer used by consular officers.[1]

Analysis of Comments

The proposed rule was published in the **Federal Register** on March 17, 2023. The comment period closed May 16, 2023. The Department received two responsive comments, both in favor of the proposed elimination of 22 CFR 42.68, and one non-responsive comment.

One of the two responsive comments advocated for replacing 22 CFR 42.68 with ''supportive and accessible eligibility screenings for noncitizens seeking visas,'' while the other comment only expressed its support for the proposed elimination. The Department has considered these comments. Considering the complexity required to evaluate a noncitizen's eligibility for a visa, and limited resources to reliably assess eligibility absent a visa application, the Department is unable to offer any eligibility screenings. Noncitizens who wish to receive a nonimmigrant or immigrant visa must formally apply for a visa to allow a consular officer to assess their eligibility for the visa.

[1] *See* the proposed rule for further discussion.

Regulatory Findings

A. Administrative Procedure Act

As this rule involves amending visa policy, which is a foreign affairs function of the United States, it is exempt from both the delayed effective date and notice and comment requirements of 5 U.S.C. 553 per subsection (a)(1). Notwithstanding the applicability of the foreign affairs exception to this rule, the Department, for its own benefit, sought public comment on the proposed elimination of 22 CFR 42.68. *See, e.g., Hoctor* v. *U.S. Dep't of Agric.,* 82 F.3d 165, 171–72 (7th Cir. 1996) (observing that there is nothing in the APA that forbids an agency's use of notice-and-comment procedures even if not required under the APA, and that courts should attach no weight to an agency's varied approaches involving similar rules). Though this rule is not subject to 5 U.S.C. 553(d), the Department is also choosing to delay the effective date of this rule for 30 days.

B. Regulatory Flexibility Act

As this rulemaking is not required to be published for notice and comment under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth by the Regulatory

Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.*

Issued on November 30, 2023.

Ross Landes,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–27257 Filed 12–12–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–1222]

Specific Listing for Three Currently Controlled Schedule I Substances

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is establishing a specific listing and DEA Controlled Substances Code Number (drug code) for three substances: *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide (also known as ADB–BUTINACA); 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (also known as α-PiHP or *alpha*-PiHP); and 2-(methylamino)-1-(3-methylphenyl)propan-1-one (also known as 3–MMC or 3-methylmethcathinone) in schedule I of the Controlled Substances Act (CSA). Although ADB–BUTINACA, α-PiHP, and 3–MMC are not specifically listed in schedule I of the CSA with their own unique drug codes, they are schedule I controlled substances in the United States because they are positional isomers of AB–PINACA (controlled January 30, 2015), α-PHP (controlled July 18, 2019), and mephedrone (controlled as a hallucinogen July 9, 2012), respectively, each of which are schedule I hallucinogens. Therefore, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include ADB–BUTINACA, α-PiHP, and 3–MMC.

DATES: Effective December 13, 2023.

FOR FURTHER INFORMATION CONTACT: Dr. Terrence L. Boos, Drug and Chemical Evaluation, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3249.

SUPPLEMENTARY INFORMATION:

ADB–BUTINACA Control

ADB–BUTINACA (also known as *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide) is a chemical substance that is structurally related to AB–PINACA (also known as *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide). AB–PINACA is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(70). The introductory text to paragraph (d) provides: (1) A listed substance includes ''any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation,'' and (2) the term ''isomer'' includes the ''optical, position[al], and geometric isomers.''

When compared to the chemical structure of AB–PINACA, ADB–BUTINACA meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term ''positional isomer'' in 21 CFR 1308.11(d). Both AB–PINACA and ADB–BUTINACA possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety between functional groups that does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), ADB–BUTINACA, as a positional isomer of AB–PINACA, has been and continues to be a schedule I controlled substance.[1]

α-PiHP Control

α-PiHP (also known as 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one or *alpha*-PiHP) is a chemical substance that is structurally related to α-PHP (also known as 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one). α-PHP is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(95). When compared to the chemical structure of α-PHP, α-PiHP meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term ''positional isomer'' in 21 CFR 1308.11(d). Both α-PHP and α-PiHP possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a rearrangement of an alkyl moiety that does not create new chemical functionalities or destroy existing chemical functionalities. Accordingly, under 21 CFR 1308.11(d), α-PiHP, as a positional isomer of α-PHP, has been and continues to be a schedule I controlled substance.[2]

3–MMC Control

3–MMC (also known 2-(methylamino)-1-(3-methylphenyl)propan-1-one or 3-methylmethcathinone) is a chemical substance that is structurally related to mephedrone (also known as 4-methylmethcathinone). Mephedrone is listed as a hallucinogenic substance in schedule I at 21 CFR 1308.11(d)(36). When compared to the chemical structure of mephedrone, 3–MMC meets the definition of a positional isomer in 21 CFR 1300.01(b), which cross-references the term ''positional isomer'' in 21 CFR 1308.11(d). Both mephedrone and 3–MMC possess the same molecular formula and core structure, and they have the same functional groups. They only differ from one another by a repositioning of an alkyl moiety. Accordingly, under 21 CFR 1308.11(d), 3–MMC, as a positional isomer of mephedrone, has been and continues to be a schedule I controlled substance.[3]

The Drug Enforcement Administration's (DEA) Authority To Control ADB–BUTINACA, α-PiHP, and 3–MMC

This rule is prompted by a letter dated May 17, 2023, in which the United States government was informed by the Secretariat of the United Nations that ADB–BUTINACA, α-PiHP, and 3–MMC have been added to Schedule II of the Convention on Psychotropic Substances of 1971 (1971 Convention). This letter was prompted by decisions at the 66th Session of the Commission on Narcotic Drugs (CND) in March 2023 to schedule ADB–BUTINACA, α-PiHP, and 3–MMC under Schedule II of the 1971

[1] AB–PINACA (and its isomers) has been subject to temporary schedule I controls since January 30, 2015, first pursuant to a final order (January 30, 2015, 80 FR 5042) and the subsequent one-year extension of that order (January 27, 2017, 82 FR 8590), and then permanently pursuant to a final rule, which continued the imposition of those controls (October 16, 2017, 82 FR 47971).

[2] α-PHP (and its isomers) has been subject to temporary schedule I controls since July 18, 2019, first pursuant to a temporary scheduling order (July 18, 2019, 84 FR 34291) and the subsequent one-year extension of that order (July 16, 2021, 86 FR 37672), and then permanently pursuant to a final rule which continued the imposition of those controls (June 1, 2022, 87 FR 32996).

[3] Positional isomers of mephedrone have been subject to permanent schedule I controls since July 9, 2012 (Synthetic Drug Abuse Prevention Act of 2012 or SDAPA, Public Law 112–144, Title XI, Subtitle D).

Convention (CND Decisions 66/5, 66/6, and 66/7). Preceding these decisions, the Food and Drug Administration (FDA), on behalf of the Secretary of Health and Human Services and pursuant to 21 U.S.C. 811(d)(2), published two notices in the **Federal Register** with an opportunity to submit domestic information and opportunity to comment on this action (August 3, 2022, 87 FR 47428 and February 17, 2023, 88 FR 10344). In each instance, FDA noted that ADB–BUTINACA, α-PiHP, and 3–MMC were already controlled in schedule I of the Controlled Substances Act (CSA) as positional isomers of AB–PINACA, α-PHP, and mephedrone, respectively, and the February 2023 notice stated that no additional permanent controls for ADB–BUTINACA, α-PiHP, and 3–MMC under the CSA would be necessary to fulfill United States' obligations as a party to the 1971 Convention.

As discussed above in this final rule, ADB–BUTINACA—by virtue of being a positional isomer of AB–PINACA—has been controlled in schedule I of the CSA temporarily since January 30, 2015 (80 FR 5042), and permanently since October 16, 2017 (82 FR 47971). α-PiHP, a positional isomer of α-PHP, has been controlled in schedule I of the CSA temporarily since July 18, 2019 (84 FR 34291), and permanently since June 1, 2022 (87 FR 32996). 3–MMC, a positional isomer of mephedrone, has been controlled in schedule I of the CSA permanently since July 9, 2012 (Pub. L. 112–144, Title XI, Subtitle D). Therefore, all regulations and criminal sanctions applicable to schedule I substances have been and remain applicable to ADB–BUTINACA, α-PiHP, and 3–MMC. Drugs controlled in schedule I of the CSA satisfy and exceed the required domestic controls of Schedule II under Article 2 of the 1971 Convention.

Effect of Action

As discussed above, this rule does not affect the continuing status of ADB–BUTINACA, α-PiHP, and 3–MMC as schedule I controlled substances in any way. This action, as an administrative matter, merely establishes a separate, specific listing for ADB–BUTINACA, α-PiHP, and 3–MMC in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for these substances. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of ADB–BUTINACA, α-PiHP, or 3–MMC, who had previously been granted individual quotas for such purposes under the drug codes for AB–PINACA, α-PHP, or mephedrone.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest (5 U.S.C. 553). ADB–BUTINACA, α-PiHP, and 3–MMC are currently controlled in schedule I as positional isomers of AB–PINACA, α-PHP, and mephedrone, respectively.

Pursuant to 5 U.S.C. 553(b) (B), DEA finds that notice and comment rulemaking is unnecessary and that good cause exists to dispense with these procedures. The addition of a separate listing for ADB–BUTINACA, α-PiHP, and 3–MMC and their DEA controlled substances code numbers in the list of schedule I substances in 21 CFR 1308.11(d) makes no substantive difference in the status of these drugs as schedule I controlled substances, but instead is ''a minor or merely technical amendment in which the public is not particularly interested.'' *National Nutritional Foods Ass'n* v. *Kennedy,* 572 F.2d 377, 385 (2d Cir. 1978) (quoting S. Rep. No. 79–752, at 200 (1945)). *See also Utility Solid Waste Activities Group* v. *E.P.A.,* 236 F.3d 749, 755 (D.C. Cir. 2001) (the ''unnecessary'' prong ''is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and public'') (internal quotations and citation omitted). This rule is a ''technical amendment'' to 21 CFR 1308.11(d) as it is ''insignificant in nature and impact, and inconsequential to the industry and public.'' Therefore, publishing a notice of proposed rulemaking and soliciting public comment are unnecessary.

In addition, because ADB–BUTINACA, α-PiHP, and 3–MMC are already subject to domestic control under schedule I as positional isomers and no additional requirements are being imposed through this action, DEA finds good cause exists to make this rule effective immediately upon publication in accordance with 5 U.S.C. 553(d)(3). DEA is concerned that delaying the effective date of this rule potentially could cause confusion regarding the regulatory status of ADB–BUTINACA, α-PiHP, and 3–MMC. ADB–BUTINACA, α-PiHP, and 3–MMC are currently controlled as schedule I controlled substances, and this level of control does not change with this rulemaking.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 14094 (Modernizing Regulatory Review)

This regulation has been drafted and reviewed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 14094. This rule is not a significant regulatory action under section 3(f) of E.O. 12866. ADB–BUTINACA, α-PiHP, and 3–MMC are already controlled substances in the United States under schedule I, as they are positional isomers of schedule I hallucinogens AB–PINACA, α-PHP, and mephedrone, respectively. In this final rule, DEA is merely making an administrative change by amending its regulations to separately list ADB–BUTINACA, α-PiHP, and 3–MMC in schedule I and to assign DEA controlled substances code numbers to these substances. A separate listing for ADB–BUTINACA, α-PiHP, and 3–MMC and their DEA controlled substances code numbers will not alter the status of these substances as a schedule I controlled substances. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The rule does not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As noted in the above section regarding the applicability of the APA, DEA determined that there was good cause to exempt this final rule from notice and comment. Consequently, the RFA does not apply.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1532, DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. However, pursuant to the CRA, DEA is submitting a copy of this rule to both Houses of Congress and to the Comptroller General.

Signing Authority

This document of the Drug Enforcement Administration was signed on December 7, 2023, by Administrator Anne Milgram. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Scott Brinks,

Federal Register Liaison Officer, Drug Enforcement Administration.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding new paragraphs (d)(102) to (104) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

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(102) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide (other name: ADB–BUTINACA)	7027
(103) 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (other names: α-PiHP; *alpha*-PiHP)	7551
(104) 2-(methylamino)-1-(3-methylphenyl)propan-1-one (other names: 3–MMC; 3-methylmethcathinone)	1259

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[FR Doc. 2023–27292 Filed 12–12–23; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0657; FRL–11567–01–OCSPP]

Dodine; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of dodine in or on Fruit, pome, group 11–10; Fruit, stone, group 12–12; Nut, tree, group 14–12; and Olive, with pit. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 13, 2023. Objections and requests for hearings must be received on or before February 12, 2024, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0657, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

15D

PROPOSED REGULATION OF THE STATE BOARD OF PHARMACY

Workshop – March 7, 2024

EXPLANATION – Matter in *italics* is new; matter in brackets [~~omitted material~~] is material to be omitted. and language in *green text* indicates prior Board-approved amendments that are in the process of being codified.

AUTHORITY: § 1, NRS 639.070

A REGULATION relating to pressurized stocking. Allowing pressurized stocking to be provided without a prescription in certain circumstances.

NAC 639.69545 Pressurized stockings. (NRS 639.070)

1. A pressurized stocking ~~that has a pressure rating of 20 millimeters of mercury or more~~ may not be sold, leased or otherwise provided to a consumer without an order from a practitioner if:

(a) The Food and Drug Administration (FDA) requires the product to be sold only on a prescription or other order of a practitioner: or

(b) The product is labeled in a manner that directs the product to be sold only on a prescription or other order of a practitioner.

2. A pressurized stocking listed in subsection 1 is medical product as defined by NAC 639.6935 and a ~~A~~ medical products provider that sells, leases or otherwise provides to a consumer a pressurized stocking ~~that has a pressure rating of 20 millimeters of mercury or more~~ shall provide training to the consumer or the consumer's family, caregiver or agent in the use, maintenance and potential problems in the use of the stocking. The training must be provided by a person who is certified by the manufacturer of the pressurized stocking in the fitting and use of the stocking.

NAC 639.6935 "Medical products" defined. (NRS 639.070)

1. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease.

2. The term does not include:

(a) Controlled substances;

(b) Dangerous drugs, except medical gases and supplies that facilitate the use of a dangerous drug, including, without limitation, normal saline and other similar inert liquids;

(c) Medical devices, equipment, supplies or gases the regulation of which is governed by any other board or agency other than the Board; and

~~(d) Pressurized stockings that have a pressure rating of less than 20 millimeters of mercury.~~

DRAFT

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16A

PROPOSED REGULATION OF THE

STATE BOARD OF PHARMACY

LCB File No. R144-23

January 3, 2024

EXPLANATION – Matter in ***italics*** is new; matter in brackets **[**~~omitted material~~**]** is material to be omitted.

AUTHORITY: § 1, NRS 453.146, 453.2182 and 639.070.

A REGULATION relating to controlled substances; adding zuranolone to the controlled substances listed in schedule IV of the Uniform Controlled Substances Act; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law authorizes the State Board of Pharmacy to add, delete or reschedule substances listed as controlled substances in schedules I, II, III, IV and V of the Uniform Controlled Substances Act by regulation. (NRS 453.146) Existing law also provides that if a substance is designated, rescheduled or deleted as a controlled substance pursuant to federal law, the Board is required, with certain exceptions, to similarly treat the substance under the Uniform Controlled Substances Act. (NRS 453.2182) This regulation adds zuranolone to the list of controlled substances set forth in schedule IV of the Uniform Controlled Substances Act, consistent with federal regulations. (21 C.F.R. § 1308.14)

Section 1. NAC 453.540 is hereby amended to read as follows:

453.540 1. Schedule IV consists of the drugs and other substances listed in this section, by whatever official, common, usual, chemical or trade name designated.

2. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any of the following narcotic drugs, including, without limitation, their salts, calculated as the free anhydrous base of alkaloid, is hereby enumerated on schedule IV, in quantities:

(a) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit; or

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxy-butane).

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV, whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

Alprazolam;

Barbital;

Bromazepam;

Butorphanol;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Daridorexant;

Delorazepam;

Diazepam;

Dichloralphenazone;

Eluxadoline;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Halazepam;

Haloxazolam;

Ketazolam;

Lemborexant;

Loprazolam;

Lorazepam;

Lorcaserin;

Lormetazepam;

Mebutamate;

Medazepam;

Meprobamate;

Methohexital;

Methylphenobarbital (mephobarbital);

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Remimazolam;

Suvorexant;

Temazepam;

Tetrazepam;

Tramadol (2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol);

Triazolam;

Zaleplon;

Zolpidem; ~~[or]~~

Zopiclone ~~[.]~~ ***; or***

Zuranolone.

4. Any material, compound, mixture or preparation which contains any quantity of fenfluramine, including, without limitation, its salts, isomers and salts of such isomers, whenever the existence of such salts, isomers and salts of isomers is possible, is hereby enumerated on schedule IV. For the purposes of this subsection, "isomer" includes, without limitation, the optical, position or geometric isomer.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including, without limitation, their salts, isomers and salts of isomers, is hereby enumerated on schedule IV:

Cathine ((+)-norpseudoephedrine);

Diethylpropion;

Fencamfamin;

Fenproporex;

Mazindol;

Mefenorex;

Modafinil;

Pemoline (including organometallic complexes and chelates thereof);

Phentermine;

Pipradrol;

Sibutramine; or

SPA ((-)-dimethylamino-1,2,diphenylethane).

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of pentazocine, including, without limitation, its salts, is hereby enumerated on schedule IV.

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Executive Secretary Report

March 6 – 7, 2024

A. Financial Report

B. Issuance of Temporary Licenses and Registrations

C. Change of Address Business List

D. Meetings with Other Health Care Regulatory Boards

E. Licensing Activities Report

F. Citations & Fines issued pursuant to NRS 632.2895

G. Legislative update

March 2024 – NVBOP Business Address Change Only

Application Received	Business Name	License Number	New Location Address	City, State and Zip
1/10/2024	CenterPoint Medical LLC	MP03118	5071 N Rainbow Blvd Suite 190	Las Vegas, NV 89130
1/24/2024	Value Pharmacy	PH04299	4921 W Craig Rd	Las Vegas, NV 89130

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 2**
- **Citation & Fine –**
  - **Other: 3**

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.870: APRN Dispensing License/pharmacy applicant appearance	06/02/22	06/02/22 – Dave revising language.	R086-22	06/29/22 07/05/22: under Dave review				
NAC 453.310: DEA Registration	10/13/22	10/19/22	R197-22	05/12/23: to Dave/ Yenh 05/26/23: Under review by Yenh/Peter 05/30/23: Hold till final rule on state specific DEA registration requirement.	11/02/23	12/07/23	12/22/23	
NAC 639.694: DME Administrator for DME Inventory at a Licensed Hospital	09/07/23	09/12/23	R058-23	10/09/23	11/02/23	12/07/23	12/22/23	
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
NAC 639: Administrative Fine in Lieu of Disciplinary Action	09/07/23	09/12/23	R057-23	10/09/23	11/02/23	12/07/23	12/22/23	

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639: Protocol for RPH to Treat OUD (AB156)	09/07/23	09/12/23	R059-23	10/19/23	11/02/23	12/07/23	12/22/23	
Regulations relating Governor Lombardo's Executive Order 003-2023. Changes in these Regulations streamline and clarify licensing requirements while ensuring public safety; and providing other matters properly relating thereto.	10/11/23	10/18/23	R100-23					
NAC 453: The proposed amendments relate to controlled substances adding synthetic cannabinoids to the controlled substances listed in Schedule I.	10/11/23	10/18/23	R101-23	11/08/23 To Dave/ Yenh for review.				
NAC 453: Add Zuranolone to Schedule IV	12/07/23	12/13/23	R144-23	01/03/24	2/6/24	3/7/24		
NAC 639: The proposed amendment ensures proper and adequate safeguards for registered nurses who participate in certain public	01/18/24	2/6/24	R013-24					

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
health programs or certain mental health services.								
NAC 639: The proposed amendment removes various provisions relating to compounding which are in conflict with current United States Pharmacopeia compounding standards.	01/18/24 03/07/24							
The proposed amendments establishes the registration requirements for certified registered nurse anesthetist, under the supervision of a physician licensed pursuant to chapter 630 or 633 or NRS, to order, prescribe, possess, and administer controlled substances, poisons, dangerous drugs and devices to treat a patient under the care of a licensed physician in a critical access hospital in preparation for surgery or childbirth, during surgery or childbirth and while a patient recovers from surgery or childbirth.	3/7/24							

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R0 Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 453: The proposed amendments relate to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I.	3/7/24							
A REGULATION relating to pressurized stocking. Allowing pressurized stocking to be provided without a prescription in certain circumstances.	3/7/24							
Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding tianeptine, hallucinogenic substances and fentanyl related substances to the controlled substances listed in Schedule I.	3/7/24							

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